A PROSPECTIVE STUDY ON METABOLIC SYNDROME IN PATIENTS WITH CARDIOVASCULAR DISEASE

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CERTIFICATE

This is to certify that the dissertation work entitled "**A PROSPECTIVE STUDY ON METABOLIC SYNDROME IN PATIENTS WITH CARDIOVASCULAR DISEASE**" was carried out by **MR. JOEL VARGHESE (26107282)** is a bonafide work carried out by the candidate under my direct supervision and guidance and submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment for the Degree of **Master of Pharmacy** in **Pharmacy Practice** at the Drug and Poison Information Center, Department of Pharmacy Practice, Kovai Medical Center and Hospital, Coimbatore, during the academic year 2011-2012.

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DECLARATION

I do hereby declare that the dissertation work entitled "**A PROSPECTIVE STUDY ON METABOLIC SYNDROME IN PATIENTS WITH CARDIOVASCULAR DISEASE**" submitted to The Tamil Nadu Dr. M.G.R Medical University, Chennai, in partial fulfillment for the Degree of **Master of Pharmacy** in **Pharmacy Practice,** was done by me under the guidance of **MR. A. VIJAYAKUMAR, M.PHARM.,** at the Department of Pharmacy Practice, KMCH College of Pharmacy, Coimbatore, during the academic year 2011-2012.

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled work "**A PROSPECTIVE STUDY ON METABOLIC SYNDROME IN PATIENTS WITH CARDIOVASCULAR DISEASE**" was carried out by **MR. JOEL VARGHESE** University Reg No. **26107282** to The Tamil Nadu Dr. M.G.R Medical University, Chennai, in partial fulfillment for the Degree of **Master of Pharmacy** in **Pharmacy Practice** is a bonafide work carried out by the candidate at the Department of Pharmacy Practice, KMCH College of Pharmacy, Coimbatore and was evaluated by us during the academic year 2011-2012.

Examination Center: KMCH College of Pharmacy, Coimbatore.
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ABBREVIATIONS

AHA	:	American Heart Association
ALT	:	Alanine Aminotransferase
AST	:	Aspartate Aminotransferase
ATP	:	Adult Treatment Panel
BMI	:	Body Mass Index
BP	:	Blood Pressure
CAD	:	Coronary Artery Disease
CHD	:	Coronary Heart Disease
CVD	:	Cardiovascular Disease
CVR	:	Cardiovascular Risk
D. BP	:	Diastolic Blood Pressure
DM	:	Diabetes Mellitus
FBG	:	Fasting Blood Glucose
FBS	:	Fasting Blood Sugar
FPG	:	Fasting Plasma Glucose
HbA_1c	:	Glycosylated Hemoglobin
HDL-c	:	High Density Lipoprotein Cholesterol
IDF	:	International Diabetic Federation

IFG	:	Impaired Fasting Glucose
IGT	:	Impaired Glucose Tolerance
LDL-c	:	Low Density Lipoprotein Cholesterol
MetS	:	Metabolic Syndrome
NCEP	:	National Cholesterol Education Program
NNT	:	Number Needed To Treat
OR	:	Odds Ratio
RR	:	Relative Risk
S. BP	:	Systolic Blood pressure
S.E	:	Standard Error
TC	:	Total Cholesterol
TG	:	Triglyceride
Type I DM	:	Type I Diabetes Mellitus
Type II DM (T2DM)	:	Type 2 Diabetes Mellitus
US	:	United States
VLDL-c	:	Very Low Density Lipoprotein Cholesterol
WC	:	Waist Circumference
WHO	:	World Health Organization
WHR	:	Waist Hip Ratio

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ABSTRACT

Metabolic syndrome (MetS) is by definition a multi system disorder, in which there is an accumulation of the different conditions that together increases the risk of Cardiovascular disease (CVD), Type 2 Diabetes Mellitus (T2DM), Chronic Kidney Disease (CKD) and is related with a number of other disorders such as sleep apnea, polycystic ovarian disorder. Insulin resistance along with visceral adiposity, dyslipidemia and chronic subclinical proinflammatory state are the main characteristic features of the MetS. The main hypothesis of the study was to assess the prevalence of the MetS in patients with CVD and to estimate the age and gender wise distribution of the syndrome among the study population. The prevalence of the MetS was assessed in 180 patients who visited the Department of Cardiology using the definitions of IDF and revised NCEP ATP III. The prospective observational study revealed a prevalence of 41% (IDF) and 44% (revised NCEP ATP III) of the MetS among the study population. The prevalence of the MetS was found to be higher in women than men, based on the IDF definition: (female-51% and male-33%) and according to the revised NCEP ATP III criteria: (female-59% and male-33%). The MetS was found to be more prevalent in the study patients with the age >60years. The variables like Body Mass Index (BMI), Waist Circumference (WC), High Density Lipoprotein- cholesterol (HDL-c), Triglycerides (TG), Systolic and Diastolic Blood Pressure (BP) and Fasting Blood Glucose (FBS) were monitored. There was a significant association between the variables such as BMI, WC, BP and FBS ($p<0.05$) with the MetS. Amid the MetS driving the twin global pandemic of T2DM and CVD there is a devastating moral, medical and economic imperative to identify those individuals with the MetS early, so that lifestyle interventions and treatment may prevent the development of T2DM and CVD.

1. INTRODUCTION

Cardiovascular disease (CVD) and Diabetes Mellitus (DM) collectively with cancer and chronic respiratory disease, are the world's leading life-takers, causing an estimated 30 to 40 million deaths each year, of which 70-80% are in low- and middle-income countries (WHO, 2008). In the midst of the intensifying tide of DM around the world, the double jeopardy of CVD and DM is set to result in a flare-up of these and other cardiovascular complications if protective measure is not taken at the right time. Type II DM affects nearly 200 million individuals' world wide and its prevalence is rapidly increasing. CVD accounts for 50% of all the fatalities in people with DM. Subsequent to any cardiac event, people with DM have twofold times higher death rate than those without (Harris P *et al.,* 2004). South Asia accounts for 30-40% of worldwide DM related Ischemic Heart Disease (IHD) deaths and 30% of stroke deaths (Colhoun HM *et al.*, 2004).

The Metabolic Syndrome (MetS) has been advocated as both a simple clinical tool for predicting DM and CVD, and the conceptual basis for understanding at least part of the pathophysiological link between metabolic risk, future DM and CVD. The clustering of metabolic risk factors with CVD and DM has been recognised for more than 80 years, but the modern concept of the MetS began when Gerald Reaven (American Endocrinologist, Stanford University School of Medicine, California, USA) proposed a conceptual framework which linked apparently distinct biological events into a single pathophysiological construct. This hypothesis argued that insulin resistance provided a common mechanism underlying the related abnormalities of blood pressure (BP), High Density Lipoprotein cholesterol (HDL-c), triglyceride (TG) and glucose tolerance. This pathophysiological concept was not proposed for clinical or epidemiological use. Later, a number of different definitions have been developed for this purpose by specialized organization like World Health Organization

(WHO), the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III), the European Group for the Study of Insulin Resistance (EGIR) and most recently, the International Diabetes Federation (IDF).

The history of MetS reflects the recognition of the concept of insulin resistance and its consequences as well as the recognition of adipose tissue as a physiologically active organ. Prof. Markolf Hanefield (Director of Centre for Clinical Studies Technical University, Dresden, Germany) and Dr. W Leonhardt was the first to say the term "Metabolic Syndrome" in 1981, they used the phrase to describe the combined prevalence of hyperlipoproteinemia, DM, hypertension, gout and obesity along with an increased prevalence of CVD, fatty liver and cholelithiasis. In 1985, Dr. Michaela Modan (Head, Biometry Unit, Department of Clinical Epidemiology, Chaim Sheba Medical Center, Israel) and his associates proposed a syndrome of insulin resistance or hyperinsulinemia as a common pathophysiological feature for obesity, hypertension and glucose intolerance, which could possibly explain their common association (Leslie B., 2005).

Gerald Reaven in a 1988 lecture to the American Diabetes Association (ADA) proposed the name “Syndrome X”. According to GM Reaven, Syndrome X was a group of associated conditions that were important in the development of coronary artery disease and included hyperinsulinemia, glucose intolerance, hyperglycemia, elevated low density lipoprotein cholesterol and hypertension all resulting from resistance to insulin mediated glucose uptake. Syndrome X has also been called “Reaven's Syndrome”.

The term "deadly quartet" was coined by Dr. Kaplan NM (Clinical Professor, Department of Internal Medicine, University of Texas Southwestern Medical Center, Dallas) for the association of obesity, hypertension, hypertriglyceridemia and glucose intolerance in which hyperinsulinemia played the key pathogenic role. Dr. Defronzo RA (School of Medicine University of Texas Health Science Center, San Antonio, USA) and Dr. Ferrannini E (Clinical Professor of Medicine, Diabetes Division, University of Texas Health Science Center. San Antonio, Texas, USA) developed the term "insulin resistance syndrome" to define a disease of Non-Insulin Dependant Diabetes Mellitus (NIDDM), arterial hypertension, dyslipidemia, atherosclerotic cardiovascular disease and obesity. Zimmet P (Director Emeritus and Foundation Head of WHO Collaborating Centre for the Epidemiology of Diabetes Mellitus) introduced the term "syndrome X plus" which included the elements of syndrome X as defined by Reaven GM, and also included upper body obesity, hyperuricemia, physical inactivity and aging. Finally, Hjerrman proposed renaming syndrome X as "metabolic cardiovascular syndrome" or "atherothrombogenic syndrome". In addition to the components of syndrome X, the presence of Low Density Lipoprotein cholesterol (LDL-c), HDL-c, Very Low Density Lipoprotein cholesterol (VLDL-c) and TG, even in the absence of hypercholesterolemia was also noticed by Hjerrman (Leslie B., 2005).

MetS is a cluster of four main CVD risk factors such as obesity, insulin resistance (hyperglycemia), hypertension and dyslipidemia; among which obesity and insulin resistance are the indispensable components. The other important entities of MetS comprise of low-grade inflammation, endothelial dysfunction, plasma hypercoagulability and atherosclerosis (Sidorenkov O *et al.*, 2010). The prevalence of MetS is linked with standard of living, demographic, socio-economic, and genetic factors (Ferreira I *et al.*, 2005). The various components such as age, BMI, postmenopausal status, diet rich in saturated fats, carbohydrates, and smoking have been positively related with MetS, while inverse links have been revealed for physical activity, education, income, and alcohol consumption (Park YW *et al.*, 2003). MetS is a comprehensive disorder and an emerging clinical challenge. Clustering together of hypertension, central obesity and dyslipidemia, with and without hyperglycemia is recognized for many decades and has been prospectively demonstrated in the Framingham study in the 1970s, and the Scandinavian studies in the 1980s (Bloomgarden ZT., 2002).

The MetS consists of a group of heart disease hazard factors, including low HDL-c, elevated TG, impaired carbohydrate metabolism, central obesity, and high blood pressure (Reaven GM., 1988) (DeFronzo RA., 1991). People with MetS have twice the risk of cardiovascular disease and four times greater risk for developing diabetes (Grundy SM., 2007). According to the IDF around 20-25 percent of the world's population has the MetS when compared to the general population and they are twice as likely to die from and thrice as likely to have heart attack or stroke (Isomaa B *et al.*, 2001).

According to George Alberti (co-author of IDF consensus) "whichever definition is used and whatever variation in the numbers due to the different criteria, when looking at prevalence data for the MetS in different countries and across various ethnic groups, one fact is clear, universally, the MetS is a huge problem and is one that is growing at an alarming rate" (IDF consensus, 2006). Further the MetS is of special interest because it represents a composite disorder expressed by interconnected risk factors with unidentified genetic and not well known environmental influences (Kraja AT *et al.*, 2005). A cardiovascular risk factor survey in France identified that elevated body weight, waist girth and low HDL-c were significantly larger contributors to the MetS in women than in men, whereas systolic and diastolic blood pressure contributed significantly less in women than in men (Dallongeville J *et al.*, 2004).

As central obesity is one of the factors included in the definition of the MetS, from the given Body Mass Index (BMI), central obesity is more common in men, is expected that prevalence of the MetS would be higher in men than in women. Among non- diabetic European men and women from eight populations the prevalence of the MetS was generally higher in men than in women (Hu G *et al.,* 2004). The effect of generalized obesity is also extremely important, in a population in which obesity is more common in women than in men. This pattern can be observed in Indian, Iranian and Turkish populations (Onat A *et al.,* 2002; Azizi F *et al.,* 2003; Gupta A *et al.,* 2003; Ramachandran A *et al.,* 2003).

The WHO defined MetS as insulin resistance and / or impaired glucose tolerance and two or more of the following:

1) Waist-Hip ratio (WHR) >0.90 (men), >0.85 (women) or Body mass index (BMI) >30 kg/m^2,

2) TG >0.9 mmol/l (men), 1.7 mmol/l (women),

3) BP >140/90 mmHg (or treated Hypertension)

4) Microalbuminuria

In 2001 the NCEP ATP III defined MetS, which was revised in 2005 by the American Heart Association/National Heart; Lung and Blood Institute. In the same year IDF proposed another definition. This definition laid prominence on abdominal obesity measured by the waist circumference. The other criteria include the elevated TG, decreased HDL-c, elevated BP and elevated fasting plasma glucose levels.

The revised NCEP ATP III defined MetS as the occurrence of any three of the following five factors:

i) Abdominal Obesity (Waist circumference): men > 90 cm; women > 80 cm (Asians)

ii) TG ≥ 150 mg/dl

iii) HDL-c: men < 40 mg/dl; women < 50 m/dl

iv) BP ≥ 130/ ≥ 85 mm Hg

v) Fasting glucose ≥ 110 mg/dl

The NCEP ATP III definition requires any three of the five criteria, whereas the IDF requires central obesity plus any of the other two abnormalities (Singh SM & Matoo SK., 2008). A more recent definition by IDF stressed the importance of waist circumference strictly and regarding the ethnic/ race specific criteria (Marc DH *et al.,* 2009).

Amongst individuals with DM, hypertension or coronary heart disease (CHD) the prevalence of the MetS is considerably higher than the general population. For example, the prevalence of MetS using WHO criteria was between 76 and 92 per cent in various European populations of people with diabetes (Bruno G *et al.,* 2004; Ilanne-Parikka P *et al.,* 2004; Relimpio F *et al.,* 2004).

The MetS is a combination of a number of factors which may share a common etiology and each of which is a risk factor for CVD and or Type 2 DM. The clustering of CVD risk factors that depicts the MetS is now considered to be the driving force for a new CAD epidemic. It is expected that abdominal weight gain reduces the life expectancy by nine years due to obesity. Weight gain and obesity are associated with increased morbidity and mortality resulting in CHD, DM, Hypertension, cancer (in particularly of esophagus, colon, stomach, liver, gall bladder, pancreas, prostate in men & breast in women) and Gall bladder disease. In general the obese population was found to get three time increase in DM, insulin resistance and dyslipidemia (Nestel P *et al.,* 2007).

CAD is the major cause of mortality and morbidity worldwide. A recent Finnish population based study suggested that Type 2 DM proven Myocardial Infarction (MI) have the same risk of MI as in non diabetics with proven MI (Qiao Q *et al.,* 2009).

In Asian Indians, there is an increasing pool of the MetS which is becoming a great concern, as much of it would convert to T2DM and CVD when effective interventions are not applied; thereby reversing the gains made through recent declining CVD mortality. Based on existing estimates, MetS affects almost 1/4th of the population in developed countries and the prevalence is still rising in developing countries, including India.

A WHO expert consultation concluded that "the MetS may be useful as an educational concept but it lacks utility as diagnostic or management tool. The different definitions of the MetS hamper its epidemiological utility. It should not be applied as a clinical diagnosis. It is, however, good practice to control the other factors when one of the signs of the metabolic syndrome is seen" (Simmons RK *et al.,* 2010). This statement dismisses the impression that identification of the MetS allows the identification of individuals with central obesity and cardiometabolic risk factors These individuals are at higher risk of clinical conditions such as T2DM, CVD, non-alcoholic fatty liver disease (NAFLD) and sleep apnea syndrome, but often the severity of the central fat accumulation, or other individual cardiometabolic risk factors is not alleged to demand pharmacological treatment because the individual factor(s) fall beneath thresholds for initiating drug treatment (Wild SH *et al.,* 2011).

"The FDA does not necessarily consider the MetS to represent a distinct disease entity" and according to the ADA and EASD (European Association for the Study of Diabetes) "the MetS requires much more study before its designation as a syndrome is truly warranted". From a pragmatic perspective, providing a label to embrace possible components of cardiovascular risk clusters acts as an *aide memoire* to prompt a search for, or monitoring of, other risk factor variables, with appropriate treatment of each emergent factor. As Shakespeare's Juliet asked "What's in a name?" MetS, or What you will, is a cardiovascular risk factor alert tag (Day C., 2007).

While there have been several studies on the prevalence of CAD in DM particularly in South India and others, the exact prevalence of the MetS and the importance of the individual components in the development of CAD is not as much of investigated in India using the revised NCEP ATP III definition. A recent study on young north Indian patients with CAD confirmed the association with MetS, but the sample size was small and all the subjects were non diabetics with normal or impaired glucose tolerance (Achari V *et al.*, 2006). This study is an attempt to enhance the available knowledge in this field, as well as to compare its relative importance with known and established risk factors. Henceforth, research is needed to establish whether there is one single factor or several which interact to give the complete characteristic picture of the MetS in patients with CVD using both the definitions of IDF and revised NCEP ATP III.

2. REVIEW OF LITERATURE

A cross sectional study was carried out in 719 patients aged greater than 13years by **Barbosa JB *et al*., (2010)** in the outpatient department of cardiology clinic in Brazil, to assess the prevalence of Metabolic Syndrome (MetS) and the related components along with the relationship between the two diagnostic criteria. They concluded that the prevalence of MetS was higher in both genders when using International Diabetes Federation (IDF) definition (62.3% in men and 64.6% in women) than when using the National Cholesterol Education Program Adult Treatment Plan III (NCEP ATP III) (48.9% in men and 59% in women) and hypertension was the most prevalent factor.

Wilson PWF *et al*., (2010) investigated whether MetS was a precursor of cardiovascular disease (CVD) and Type 2 Diabetes Mellitus (T2DM). A cohort study was conducted in 3323 middle-aged adults over an 8-year period to study the development of CVD and T2DM. During baseline in people without CVD or T2DM, the prevalence of the MetS was found to be 26.8% in men and 16.6% in women. The study concluded that MetS is commonly associated with an increased risk for CVD and T2DM in both genders.

In 2009 **Misra R *et al***., studied the prevalence of diabetes, MetS and cardiovascular risk factors among 1038 randomly selected Indian immigrants in the United States, aged from 18 years. The prevalence rate of Diabetes Mellitus (DM) was found to be 17.4%, and pre-diabetes was found in 33% of the subjects. Cardiovascular risk factors, mainly higher levels of Triglyceride (TG), Total Cholesterol (TC), Low Density Lipoprotein cholesterol (LDL-c), homocysteine, and C-reactive protein, and lower levels of High Density Lipoprotein cholesterol (HDL-c), were observed. The age-adjusted incidence of MetS was established to be 26.9% by using the original NCEP ATP III criteria, 32.7% by the revised NCEP ATP III criteria, and 38.2% by the IDF criteria.

A survey was conducted in United States by **Ford ES *et al*., (2004)**, amongst 6,436 men and women aged from 20 years with the National Health and Nutrition Examination Survey (NHANES) III (1988–1994) and about 1,677 participants from NHANES 1999–2000, using the NCEP ATP III definition. The study concluded that the unadjusted prevalence of the MetS was 23.1% in NHANES III and 26.7% in NHANES 1999–2000, and the age-adjusted prevalence were 24.1% in NHANES III and 27.0% in NHANES 1999–2000. The age-adjusted prevalence increased by 23.5% in women and 2.2% in men.

Sawant A *et al*., (2011) conducted a population-based survey in the metropolitan city of Mumbai. About 548 subjects, who attended the evaluation camp, were included in the study. The revised NCEP ATPIII was used to define MetS, and found that almost 95% of the participants had at least one abnormal factor. The prevalence of MetS was about 19.5%. The prevalence of MetS in males was nearly twice than females. The overall prevalence of Body Mass Index (BMI) (>23 kg/m^2) was about 79.01%. Hypertriglyceridemia and decreased levels of HDL-c were found to be more in males.

A study was undertaken by **Afsana F *et al*., (2010)** in Dhaka Bangladesh to identify the parameters of MetS to predict CVD and Peripheral Vascular Disease (PVD). A total of 360 subjects were selected; among them 260 subjects were categorized in group 1 , who reported for Coronary Angiogram (CAG) and 100 subjects (group 2) were selected from outpatient department, coming for follow up with no past history of Coronary Artery Disease (CAD). Among the subjects 64.6% of group 1 and 66% of group 2 subjects had MetS. Among the CAG positive subjects 38.83% had single, 30.09% had double and 31.08% had triple vessel disease, 62.1% had increased waist circumference (WC), 90% had dyslipidemia and dysglycemia. This study reveals that hypertriglyceridemia, WC and hypertension are highly significantly while PVD is not higher in CAG positive subjects and there is no evidence of the relationship between MetS and PVD.

In this study, **Hwang IC *et al*., (2011)** investigated whether and to what extent MetS and its individual components are related to the risk of CVD in Korean population. Data from the 2005 Korea National Health and Nutrition Examination Survey were used for the study. The study sample consisted of 1,406 Korean adults (587 men, 819 women) who were diagnosed with MetS based on the revised NCEP ATP III criteria. The CVD prevalence among the subjects was 6.8% for men and 8.6% for women. Fasting glucose level was the highest predicting factor for CVD in Korean patients with MetS based on the revised NCEP ATP III definition.

Yang T *et al*., (2012) explored the association between MetS related indicators and the ten-year risk for CVD in the middle-aged and elderly population. Data were collected from residents in Southern Taiwan through a health screening program, carried out from March 2007 to May 2008. Subjects with abdominal obesity and hypertension had significantly higher risk for CVD than those who had normal WC and blood pressure (BP). Subjects with hypertriglyceridemia were 1.86 times more at risk for developing medium risk of CVD than those who had normal triglyceride levels. Moreover, individuals with decreased HDL-c had significantly higher risk for CVD than those who had normal HDL-c. It was revealed that WC, BP, TG and HDL-c might be the positive indicators for predicting the risk of CVD for middle-aged and elderly populations.

In Canadian adults **Brenner DR *et al*., (2011)** explored the changes in the profile of a number of metabolic and inflammatory markers associated with cardiometabolic disease at various stages of MetS. Serum levels of apolipoprotein A1 and B (Apo- A1 and B), HDL-c, fibrinogen, glycosylated haemoglobin (HbA_1C) and homocysteine were determined in 1,818 non-diabetic adults (16-79 years of age) from the Canadian Health Measures Survey. The prevalence of the MetS was 8.9%, with 31.8% having atleast one component in common. Metabolic markers such as HDL-c, Apo-B and HbA_1C were increased significantly whereas

Apo-A was decreased. A significant association was observed between the MetS components and C-reactive protein and fibrinogen, but not homocysteine.

The association of BMI and MetS along with the risk of CVD in middle-aged men of Sweden was investigated by **Arnlov J *et al*., (2010)**. About 1758 participants without diabetes of 50 years age were assessed for cardiovascular risk factors. During follow-up (median 30 years), 681 developed CVD. Middle-aged men with MetS had greater risk for coronary events. In contrast to earlier reports, overweight and obese persons without MetS also had an increased risk of CVD.

A population based, prospective cohort study was conducted by **Lakka HM *et al*., (2002)** to assess the association of MetS with cardiovascular and overall mortality in about 1209 Finnish middle aged men without CVD, cancer or DM, aged 42-60 years at baseline. CVD and all-cause mortality are higher in men with MetS, even in the absence of baseline CVD and DM. The prevalence of MetS ranged from 8.8% to 14.3% depending on World Health Organization (WHO) and NCEP ATP III definition.

A systemic review and meta analysis conducted by **Mottillo S *et al*., (2010)** identified 87 studies which included 9,51,083 patients (NCEP ATP III: 63 studies, 4,97,651 patients; revised NCEP ATP III: 33 studies, 4,53,432 patients).There was little difference between the cardiovascular risk related with NCEP ATP III and revised NCEP ATP III definitions. When both definitions were evaluated MetS was associated with an increased risk of CVD. Patients with MetS, but without DM, had a higher choice of cardiovascular risk.

Sidorenkov O *et al*., (2010) did a cross sectional study on 3555 adults aged between 18-90 years in Russia. MetS was defined using IDF and NCEP ATP III criteria. Factors such as BMI, age, serum Gamma-glutamyltransferase (GGT), C-reactive protein and Aspartate aminotransferase (AST) to Alanine-aminotransferase (ALT) ratio were correlated with MetS in both genders. MetS was associated with sedentary lifestyle and smoking in women and men respectively. In the same regression model drinking alcohol 2-4 times a month and consumption of five or more alcohol units at one occasion in men, and drinking alcohol 5 times or more a month in women were inversely associated with MetS. After a 9-year follow-up, MetS was associated with higher risk of death from stroke and from either stroke or myocardial infarction (MI) in men. A positive association between MetS and mortality were observed for deaths from stroke and or MI in men.

Guzder RN *et al*., (2006) investigated the prognostic implication of MetS according to revised NCEP ATP III criteria and the implication of individual features of MetS on CVD and Coronary Heart Disease (CHD) in a 5-year community based study of people with newly diagnosed T2DM About 562 participants aged 30-74 were grouped into a cross sectional study and 428(without CVD) participants into a prospective analysis. MetS was independently associated with CVD and CHD on diagnosis of T2DM. Increased age, female gender, TC and lipid-lowering therapy were also independent predictors of the risk. MetS at baseline was associated with an increased risk of CVD in the 5 years following diagnosis of T2DM. With the increase in MetS features, there was a decline in the CVD-free survival rates.

Chien KL *et al*., (2008) investigated the distribution, agreement and classification patterns of MetS among the ethnic Chinese population. A total of 6610 (women, 42.5%) adults (mean age, 52.3 years) were included in the study. The criteria of MetS was divided into two groups: those with a major component required (WHO, EGIR [European Group for the Study of Insulin Resistance], AACE [American Association of Clinical Endocrinologist], IDF) and those with equal component (ATP III, American Heart Association/National Heart, Lung and Brain Institute [AHA/NHLBI], with modifications). The highest standardized rates were in Asian AHA criterion, up to 29.8% in men and 25.6% in women. The lowest rates were in WHO criterion, 8.8% in men and 8.0% in women.

Al-Shaiji *et al*., (2007) determined the prevalence of MetS and the main characteristics associated with it, of adults attending two obesity clinics in Kuwait. A cross sectional study using the data collected from 617 adults aged 15 years and over was selected. Most of the patients were found to be obese (74.2%); along with low HDL-c, hypertriglyceridemia, increased WC, and high BP. The prevalence of MetS using NCEP ATP III was 46.8%.

A prospective study was conducted in the Northern region of Ghana by **Titty FK (2010)**, to establish the relationship between glycemic control, dyslipidemia and MetS. The incidence of good glycemic control, poor glycemic control, dyslipidemia and MetS among the patients were 96 (40.0%), 144 (60.0%), 164 (68.3%) and 104 (43.3%) respectively. Dyslipidemia occurred in 56 (58.3%) of the patients with good glycemic control and 108 (75.0%) of those with poor glycemic control. MetS was diagnosed according to NCEP ATP III criteria and occurred in 32 (33.3%) of the patients with good glycemic control and 72 (50.0%) of the patients with poor glycemic control.

Jordan HT *et al*., (2012) studied the prevalence of and factors associated with MetS among adult New York City residents aged 20 years or older with the help of the 2004 New York City Health and Nutrition Examination Survey. The prevalence of MetS and its components was defined by the revised NCEP ATP III guidelines, among a probability sample of 1,263 participants. The age-adjusted prevalence of MetS was 26.7%. The incidence was highest among Hispanics (33.9%) and lowest among Whites (21.8%). The occurrence increased with age and BMI and was higher among women (30.1%) than men (22.9%). The most frequent combination of metabolic abnormalities was abdominal obesity, elevated fasting blood glucose, and BP. After adjusting for other factors, higher BMI, Asian race, and current smoking were positively relatively with MetS; alcohol use was inversely associated with MetS among women but increased the likelihood of MetS among men.

A cross-sectional survey on the MetS and associated risk factors was performed by **Kaur P *et al*., (2010)**. The MetS was defined using IDF and using revised NCEP ATP III criteria. The analysis of the obtained data revealed the prevalence of the MetS as 41.3% and 51.4% using IDF and AHA/NHLBI criteria respectively. The prevalence of MetS was very high in the industrial population of south India.

A cross sectional study by **Das M *et al*., (2010)** was carried among 350 individuals aged 30 years and above, of which 184 and 166 were men and women respectively. The prevalence was significantly higher in females (48.2%) when compared to males (16.3%). It was observed that males without MetS had significantly higher WC, waist-hip ratio, TG, Very Low Density Lipoprotein cholesterol (VLDL-c) and fasting blood glucose as compared to females without MetS.

The prevalence of DM and MetS in Slovakia was explored by **Mokan M *et al*., (2008)**, among 1517 subjects. The prevalence of MetS according to NCEP ATP III criteria was found to be 20.1% i.e.(15.9% in males and 23.9% in females) and 38.1% according to IDF criteria (39.7% in males and 36.6% in females). The most widespread MetS component was lower levels of HDL-c among the subjects.

Using the data from the National Health and Nutrition Survey 2006 **Rojas R *et al*., (2010)** examined the prevalence of Mets and its contributing risk factors in Mexican adults aged 20 years and older. In accordance with definitions by the NCEP ATP III, AHA/NHLBI, and IDF, the prevalence of MetS was 36.8, 41.6 and 49.8%, respectively. Women were more affected than men due to the higher prevalence of central obesity among females. Prevalence of MetS increased with age and was higher among populations living in metropolitan areas, in the west-central region, and those with lower education.

Luksiene DI *et al*., (2010) compared the prevalence of the MetS using three different definitions and evaluated its associations with Ischemic Heart Disease (IHD) in Kaunas adult population of Lithuania. A total of 1336 subjects aged 35–64 years (603 men and 733 women) were included in the study. The MetS was defined by the WHO, NCEP ATP III, and IDF criteria. IHD was diagnosed based on if a documented history of myocardial infarction, angina pectoris, or ischemic changes on electrocardiogram were predominant. The MetS diagnosed using the WHO definition was not associated with a significant risk of IHD in men and women. When using the IDF criteria the prevalence of MetS was relatively higher in both genders.

A study was conducted in a cardiac center in Patna, India by **Achari V *et al*., (2006)** investigated the prevalence of MetS and its association with CAD in 928 (602 males, 326 females) patients with T2DM using the criteria of Alberti and Zimmet. Of which 596 (64.2%) found to have MetS and 516 (55.6%) had chances for CAD. When the individual components of the MetS were tested for their relationship with CAD, it was found that obesity and microalbuminuria had the strongest association with the presence of IHD. Hypertension showed a weaker correlation while elevated TG levels showed no association. Smoking was strongly associated with the presence of CAD. The other factors associated with CAD were MetS, obesity, hypertension, nephropathy, age and smoking.

A cross-sectional study was conducted in a primary care hospital by **Cortes-Diaz N *et al*., (2011)**. About 16,856 individuals (age 58.1 +/- 15.1 years) were included in the study. The prevalence of MS adjusted for gender, age and region size according to the 2001 and 2004 NCEP-ATP III, IDF and AHA/NHLBI definitions was

28.4%, 32.8%, 65.5% and 69.4%, respectively. Hypertension was the most prevalent risk factor associated with CAD and stroke. In accordance to the AHA/NHLBI criteria, MetS appears to be the best predictor of CAD and stroke in the Portuguese population.

In 2007 **Saberi HR** ***et al***., **(2011)** conducted a cross sectional study to determine the prevalence of MetS among bus and truck male drivers in Kashan a city in Iran. From among the 429 subjects prevalence of MetS was 35.9% using NCEP ATP III criteria. Hypertension and DM were seen in 42.9% and 7% of the drivers respectively. High TG (53.4%) and low HDL-c levels (48.7%) were more common than other components of MetS. A significant positive relationship was seen between BMI, DM, high BP and MetS; but there was no association between MetS and smoking.

A retrospective study conducted in Romania by **Leon MM** ***et al***., **(2010)** identified the correlation between MetS and CVD. About 1463 patients were included in the study of which 734 patients met the diagnostic criteria of cardiometabolic syndrome. The incidence of cardiometabolic syndrome was highly predominant on the age group 40-59 years (61.66%). Increased hypertension was found in the patient age group 48-69 years (53.70%) and lowest in the patients group 25-38 years (11.35%). The study concluded that MetS was a predictor of the occurrence and development CVD.

In a community based cross sectional study **Mangat C** ***et al***., **(2010)** determined the prevalence and socio-demographic factors associated with MetS in a total of 605 subjects adults aged 18 years and above in Chandigarh, India using the IDF and NCEP ATP III criteria. By using the IDF definition, MetS was found in 287 (47.4%) subjects and it was more prevalent among females 171 (59.6%) as compared to males 116 (40.4%). By applying NCEP ATP III overall prevalence was less i.e. 233 (38.5%) but again its prevalence was more among females 141 (44.8%) than males 116 (39.5%). Higher socioeconomic status, sedentary occupation and high BMI were significantly associated with MetS.

A population based study on a sample of 5632 individuals aged 65-84 years at baseline conducted by **Maggi S *et al*., (2006)** assessed the prevalence of MetS by diabetic status and gender in the participants in the Italian Longitudinal Study on Aging (ILSA). The association of MetS with stroke, CHD, and DM at baseline and with CVD mortality at 4-year follow-up was measured. The prevalence of MetS was 25.9% in non-diabetic men and 55.2% in non-diabetic women; in diabetic individuals it was 64.9% and 87.1% in men and women, respectively. At baseline, in both men and women there was a significant association with stroke and DM. A significant association with CHD was found in men only. During the approximately 4-year follow-up, non-diabetic men with MetS had a risk of CVD mortality 12% higher compared to those without MetS, whereas no significant differences were found in women.

In Kuala Lumpur population **Moy FM *et al*., (2010)** studied the incidence of MetS using the IDF and the revised NCEP ATP III definitions and also verified if all participants have the same cardiometabolic risks. MetS was diagnosed in 41.4% and 38.2% participants using the revised NCEP ATP III and IDF criteria respectively. Participants diagnosed by the revised NCEP ATP III criteria had lower BMI and WC but had increased cardiometabolic risks than those diagnosed with both criteria. Their BP, fasting blood glucose, TC and TG were more adverse than the IDF group. This demonstrated that central obesity may not be a prerequisite for the development of increased cardiometabolic risks within the Malay population.

3. METHODOLOGY

OBJECTIVES:

- The pattern of Metabolic Syndrome (MetS) in patients with cardiovascular disease (CVD) remains ambiguous. This study sought to establish the prevalence of the MetS and the factors associated with this syndrome.
- The aim of the study was to assess the prevalence of the MetS among patients with CVD using the revised National Cholesterol Education Program Adult Treatment Plan III (rNCEP ATP III) and International Diabetes Federation (IDF) definitions.
- To assess the age related prevalence of the MetS among men and women.
- To account for prevalence of different components associated with the MetS in men and women.
- To determine the socio-demographic factors associated with the MetS.
- To categorize and compare the MetS according to the criteria of rNCEP ATP III and IDF guidelines.

STUDY DESIGN:

A prospective observational study was conducted in the outpatient Department of Cardiology, Kovai Medical Center and Hospital, a multispecialty hospital in Coimbatore. It was approved by the KMCH ethics committee for research at Kovai Medical Center and Hospital, Coimbatore on 22-10-2011.

STUDY SITE:

The study was conducted in the outpatient Department of Cardiology, Kovai Medical Center and Hospital, a multi-specialty hospital in Coimbatore.

STUDY PERIOD:

The study was carried over a period from June 2011 to December 2011 in Kovai Medical Center and Hospital, Coimbatore.

INCLUSION CRITERIA:

Both male and female patients having CVD were included in the study.

EXCLUSION CRITERIA:

Pregnant women and patients with abdominal ascites were excluded from the study.

SOURCES OF DATA:

The data was collected from various sources such as patient's case report, treatment chart and laboratory reports.

STUDY DESIGN PROTOCOL:

Patients information such as demographics, socio-economic status, physical manifestation and also clinical manifestations like fasting blood glucose value, High Density Lipoprotein cholesterol (HDL-c), Triglycerides (TG), Total Cholesterol (TC) and Low Density Lipoprotein-cholesterol (LDL-c) during baseline and review were collected.

The concept of MetS was defined according to the IDF guidelines and the diagnosis is made when increased waist circumference is present plus atleast two other risk factors.

1. Central obesity: waist circumference(WC) $\geq$ 90 cm (male), $\geq$ 80 cm (female)
2. Dyslipidemia: TG $\geq$ (150 mg/dl)
3. Dyslipidemia: HDL-c $<$ 40 mg/dl (male), $<$ 50 mg/dl (female)

4. Blood pressure (BP) ≥ 130/85 mmHg

5. Fasting plasma glucose ≥ (110 mg/dl)

The rNCEP ATP III (Asians) requires at least three of the following:

1. Central obesity: WC ≥ 90 cm (male), ≥ 80 cm (female)
2. Dyslipidemia: TG ≥ (150 mg/dl)
3. Dyslipidemia: HDL-c < 40 mg/dl (male), < 50 mg/dl (female)
4. Blood pressure ≥ 130/85 mmHg
5. Fasting plasma glucose ≥ (110 mg/dl)

The rNCEP ATP III criteria suggested the cut-off values of WC should be ethnic specific, individuals of Asian origin should use the cut-off of 90 cm in men and 80 cm in women. In the case of rNCEP ATP III definition, abdominal obesity is a part of the syndrome but not a prerequisite for its diagnosis. The IDF's diagnosis of MetS gives prominence on abdominal obesity as a mandatory factor plus any two of the other four criteria which are basically the same to those provided by rNCEP ATP III. The IDF definition uses ethnic-specific waist circumference cut-off points as a prerequisite for diagnosis. Similar to the rNCEP ATP III criteria, IDF recommends cut-off levels of 90 cm in men and 80 cm in women for central obesity among Asians. For both criteria, we used the recommended cutoff for Asians (90 cm in men and 80 cm in women) as there are no nationalized cut-off values particularly for Indians.

Statistical Analysis

The statistical package Graph Pad Prism (version 5.0) was used for statistical analysis. Differences of the mean values of baseline and review characteristics and prevalence of metabolic syndrome and its individual components of the MetS between the two study time points were tested by χ^2 test for categorical variables and odds ratio and relative risk was also calculated. Based on the definitions of IDF and rNCEP ATP III, patients were categorized and analyzed for clinical significance ($p < 0.05$) among study population.

4. TABLES AND GRAPHS

Table 1: GENERAL CHARACTERISTICS OF THE STUDY SUBJECTS

S. No.	General Characteristics	Male (Mean±S.E)	Female (Mean±S.E)
1	Number of Patients (%)	98(54%)	82(46%)
2	Age in years	54±1.25	55.52±1.38
3	BMI in kg/m²	27.27±0.38	28.20±0.34
4	Waist Circumference in cm	87.97±0.92	84.26±0.82
5	Systolic BP in mmHg	128.57±1.70	130.97±1.77
6	Diastolic BP in mmHg	81.12±1.05	83.17±1.06
7	FBS in mg/100ml	132.61±6.09	156.02±8.33
8	HDL-c in mg/100ml	47.84±0.98	40.24±1.02
9	Triglycerides in mg/100ml	130.51±5.99	110.04±3.96

Figure 1: MEAN PHYSICAL VARIABLES OF THE STUDY POPULATION

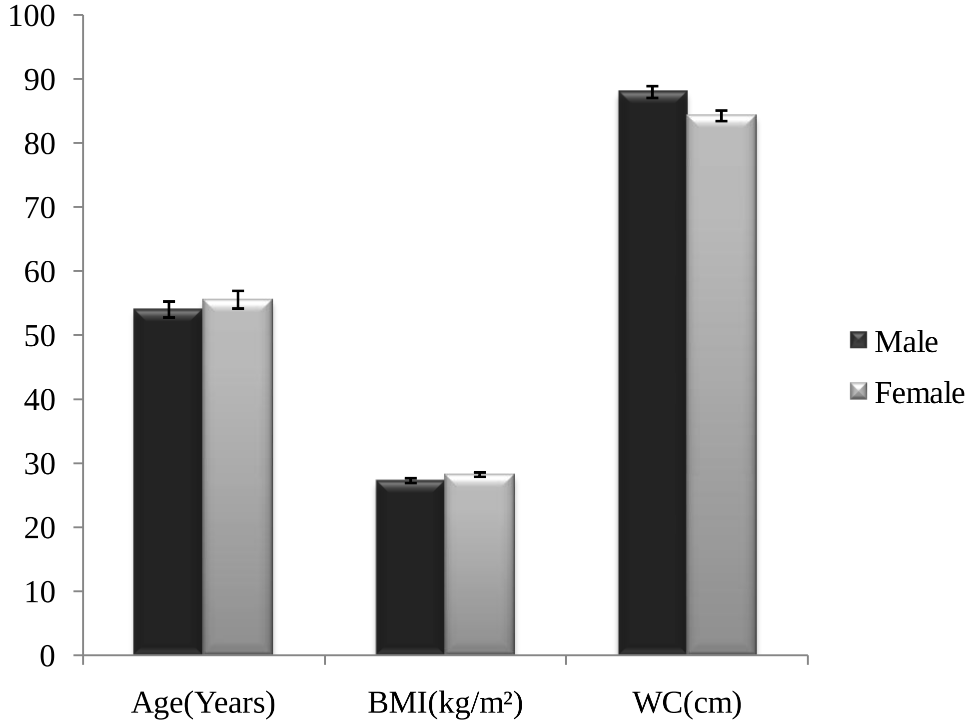

Figure 2: MEAN LABORATORY AND HEMODYNAMIC VARIABLES OF THE STUDY POPULATION

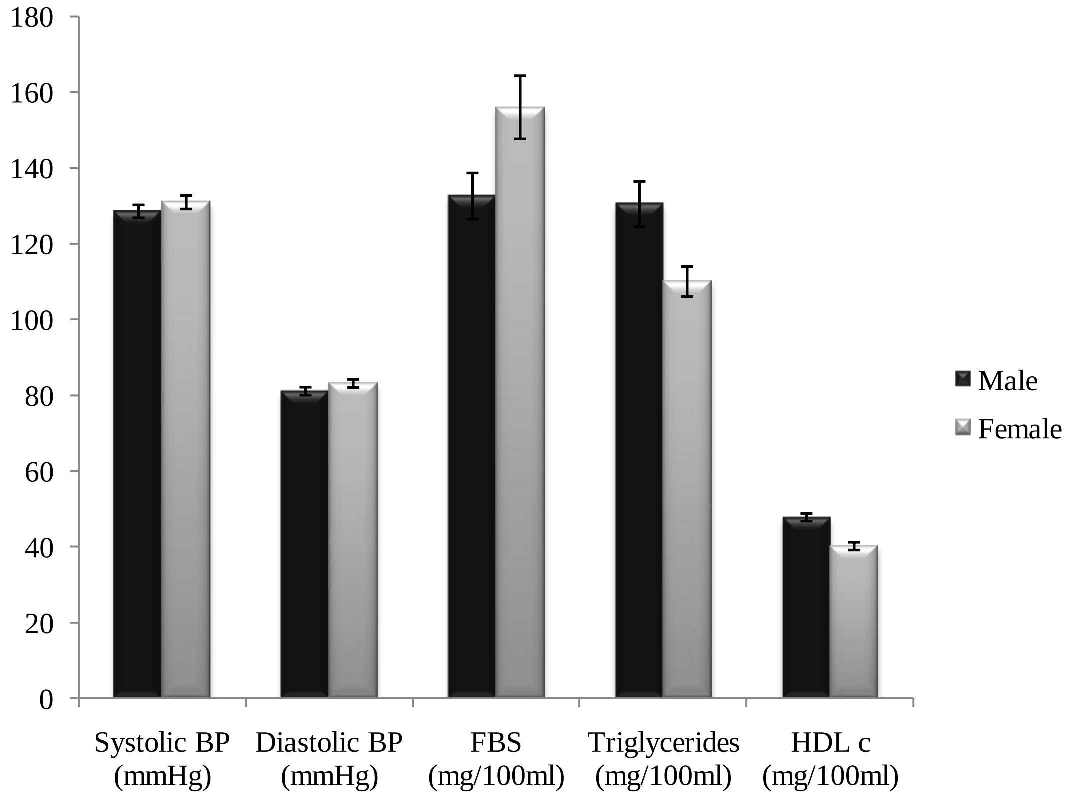

Table 2: GENDER WISE DISTRIBUTION OF THE STUDY SUBJECTS

S. No.	Gender	Total (n=180)	Percentage
1	Male	98	54%
2	Female	82	46%

Figure 3: GENDER WISE DISTRIBUTION OF THE STUDY SUBJECTS

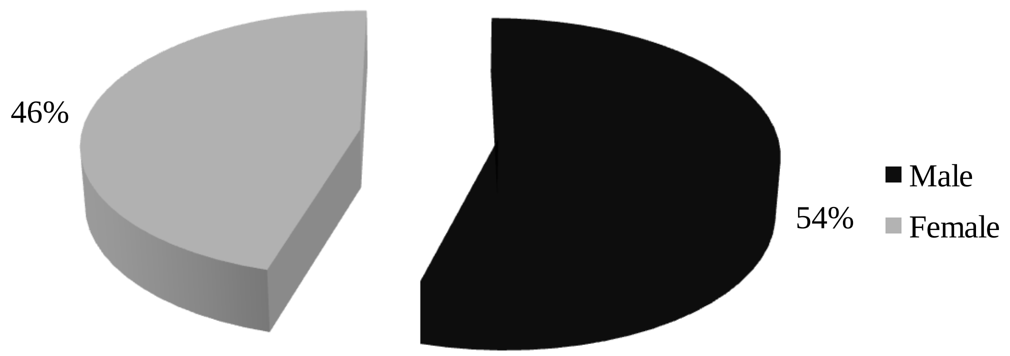

Table 3: AGE WISE DISTRIBUTION OF THE STUDY POPULATION

S. No.	Age (Years)	Total (n=180)	Percentage (%)
1	20-39	22	12.22
2	40-59	100	55.56
3	60-79	58	32.22

Figure 4: AGE WISE DISTRIBUTION OF THE STUDY POPULATION

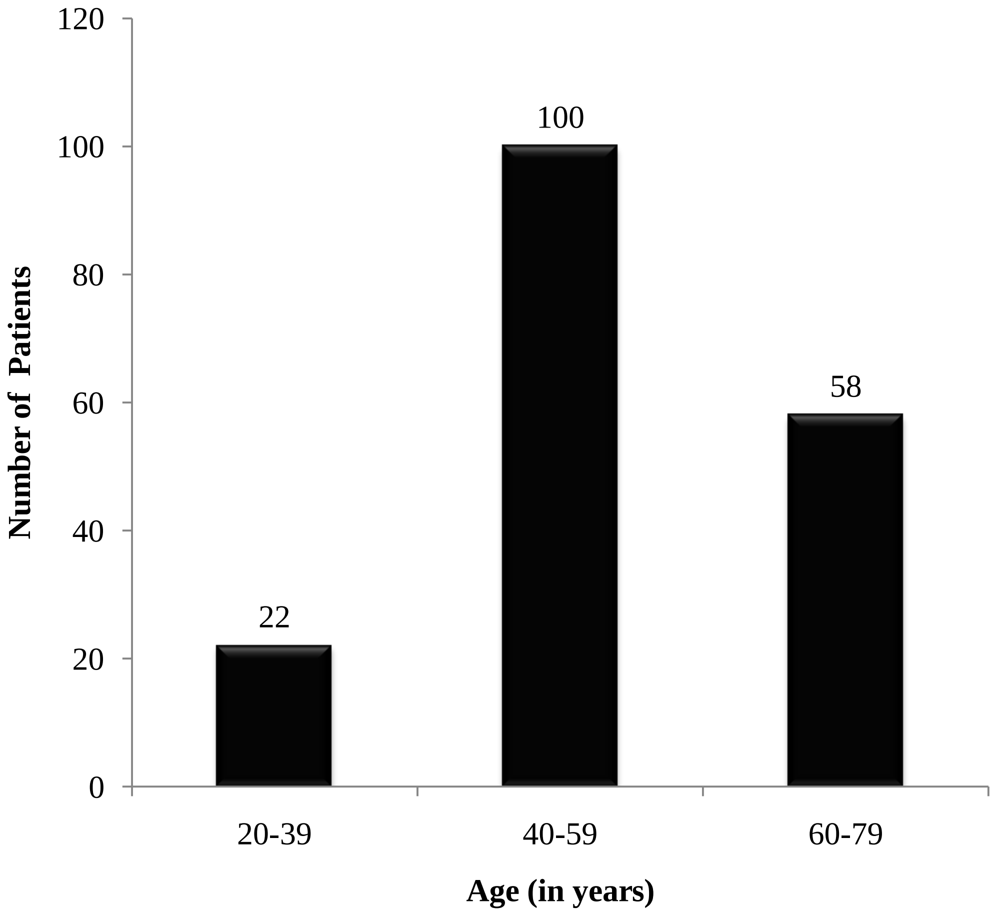

Table 4: DISTRIBUTION OF THE SUBJECTS ACCORDING TO THE MARITAL STATUS

S. No.	Marital Status	N=180	Percentage (%)
1	Single	6	3.33
2	Married	174	96.67

Table 5: DISTRIBUTION OF THE STUDY POPULATION ACCORDING TO THEIR SOCIAL HABITS

S. No.	Lifestyle Variables	N=180	Percentage (%)
1	Smoking	20	11.11
2	Alcoholic	10	5.55
3	Both Smoking & Alcoholic	40	22.22
4	None	110	61.11

Table 6: DISTRIBUTION OF THE SUBJECTS ACCORDING TO THE EDUCATIONAL STATUS

S. No.	Educational Status	N=180	Percentage (%)
1	≤ 8	78	43.33
2	9 to 11	57	31.67
3	≥ 12	45	25.00

Figure 5: DISTRIBUTION OF THE SUBJECTS ACCORDING TO THE EDUCATIONAL STATUS

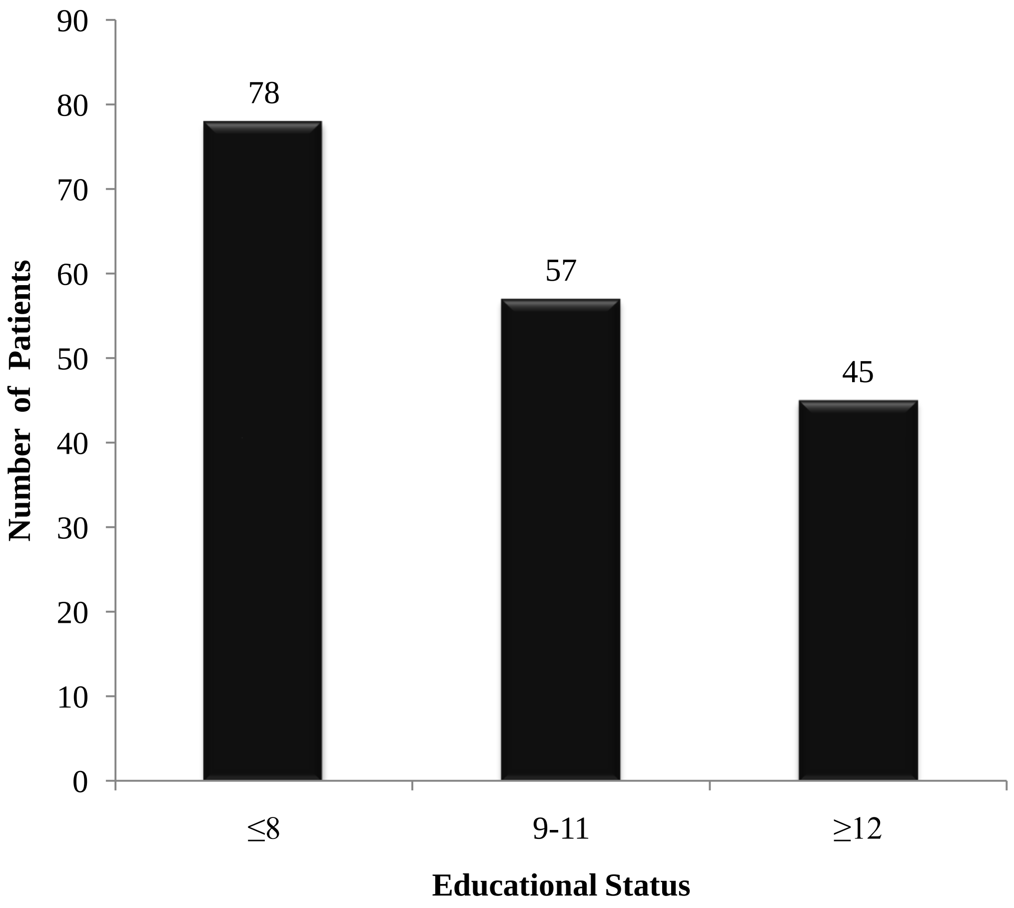

Table 7: PREVALENCE OF MetS AMONG THE STUDY POPULATION BASED ON IDF CRITERIA

S. No.	Variables	N=180	Subject with MetS (N=74)	Percentage (%)
1	**Age(in years)**			
	a. 20-39	22	6	27.27
	b. 40-59	100	36	36.00
	c. 60-79	58	32	55.17
2.	**Sex**			
	a. Male	98	32	32.65
	b. Female	82	42	51.22
3.	**Marital status**			
	a. Single	4	1	25.00
	b. Married	176	73	41.47
4.	**Educational status**			
	a. ≤ 8	78	42	53.84
	b. 9-11	57	20	35.08
	c. ≥ 12	45	12	26.67
5.	**Lifestyle Variables**			
	a. Smoking	20	6	30.00
	b. Alcoholic	10	1	10.00
	c. Both	40	27	67.50
	d. None	110	40	36.36

Table 8: PREVALENCE OF MetS AMONG DIFFERENT AGE GROUPS BASED ON IDF CRITERIA

S. No.	Age Group	With MetS	Without MetS	P value
1	20-39	6	16	
2	40-59	36	64	0.023*
3	60-79	32	26	

***p*<0.05**

Figure 6: PREVALENCE OF METS AMONG DIFFERENT AGE GROUPS BASED ON IDF CRITERIA

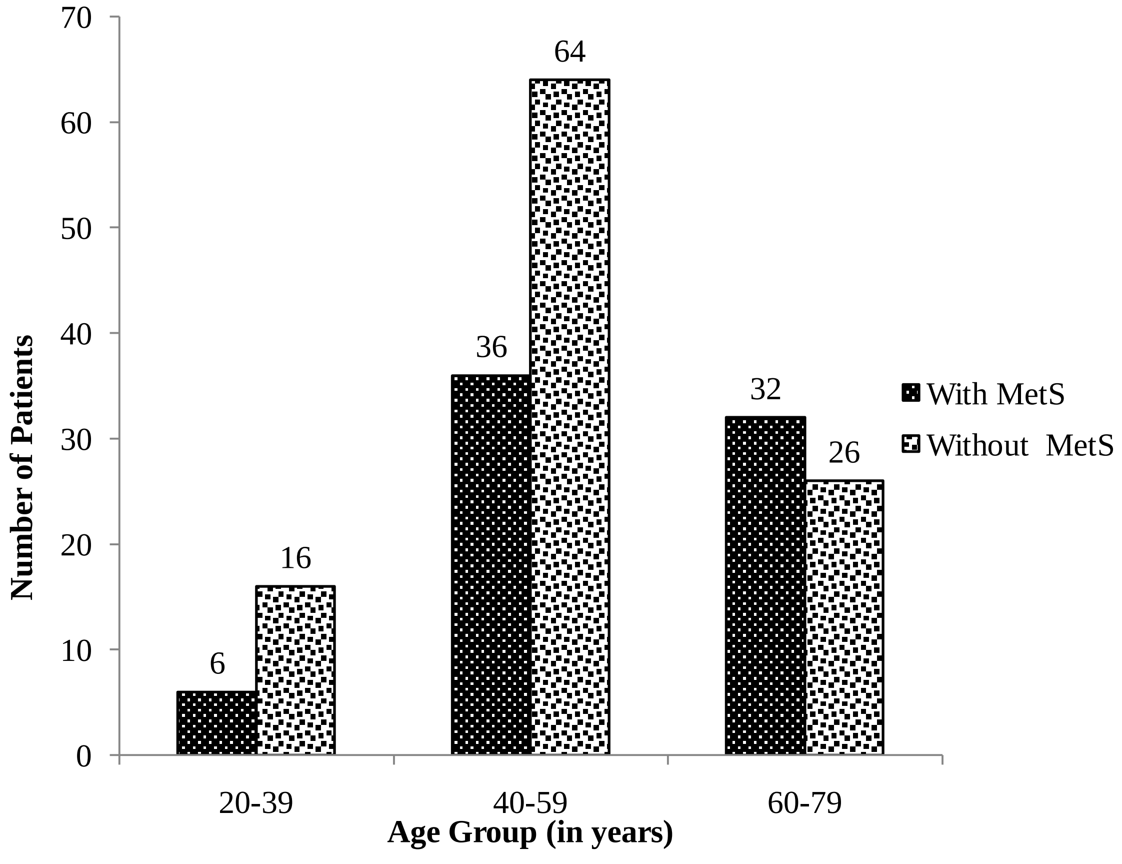

Figure 7: GENDER WISE PREVALENCE OF METS ACCORDING TO IDF CRITERIA

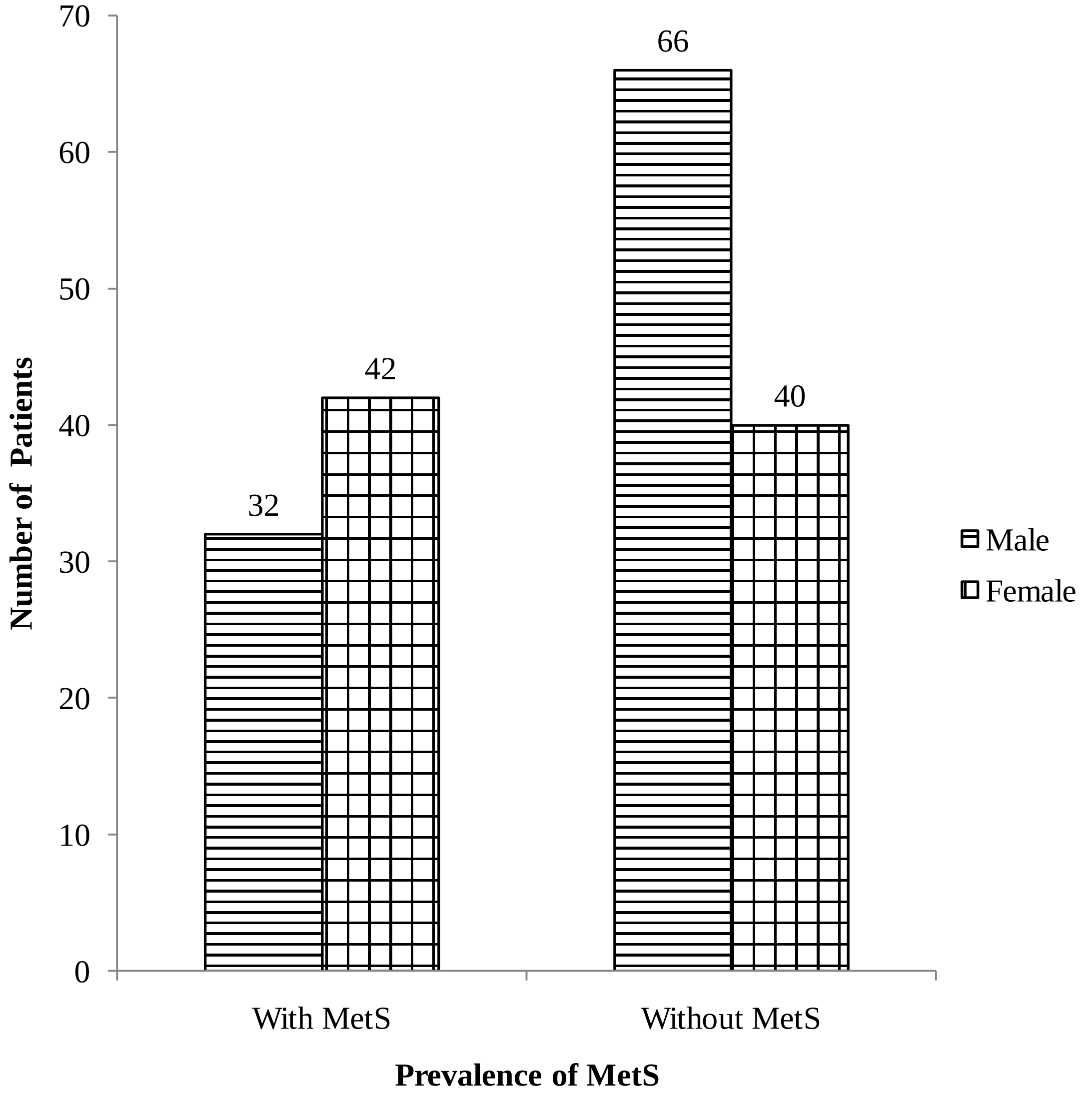

Table 9: PREVALENCE OF METS WITH RESPECT TO EDUCATIONAL STATUS BASED ON IDF CRITERIA

S. No.	Educational status	With MetS	Without MetS	P value
1	≤ 8	42	36	0.007
2	9 – 11	20	37	
3	≥ 12	12	33	

Figure 8: PREVALENCE OF METS WITH RESPECT TO EDUCATIONAL STATUS ACCORDING TO IDF CRITERIA

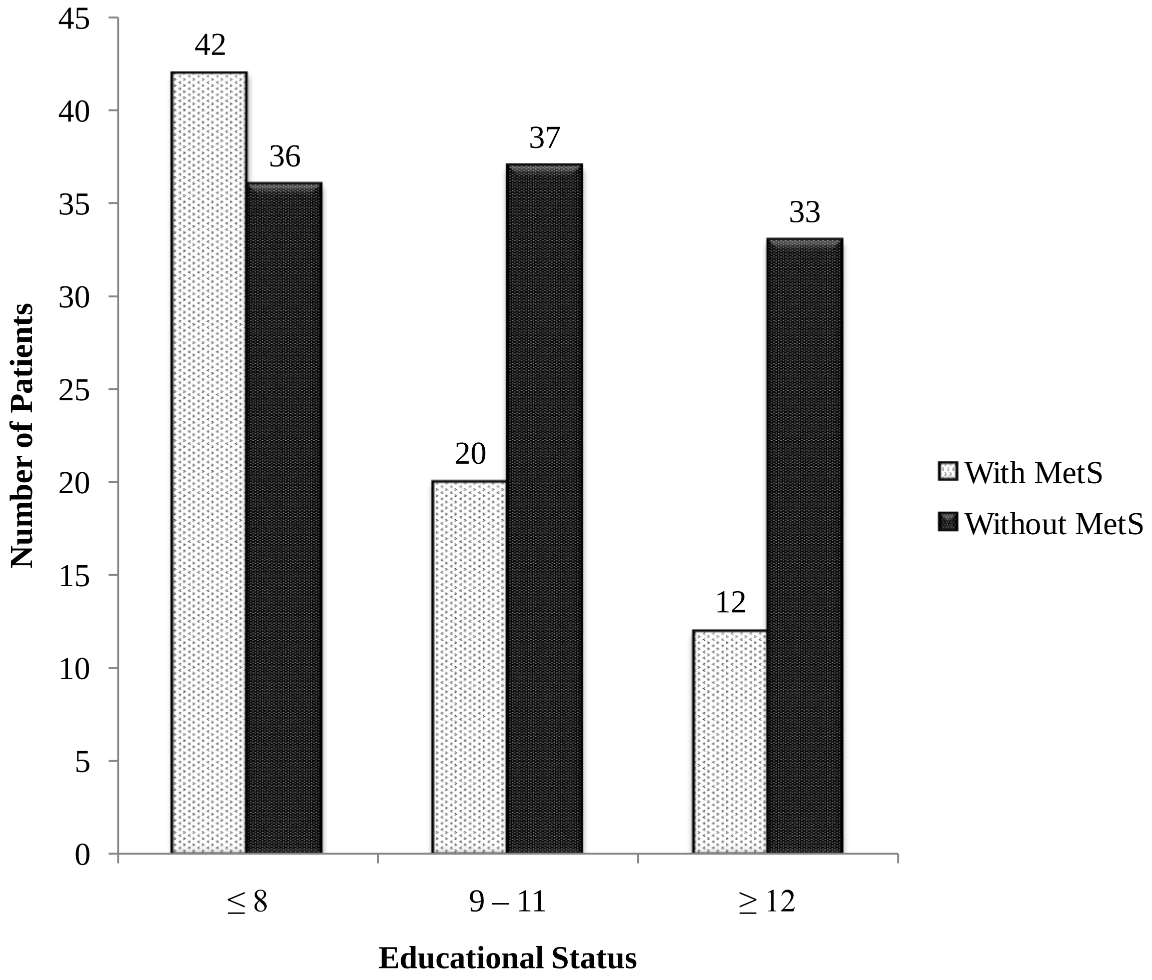

Table 10: IDF BASED DESCRIPTION OF METS ACCORDING TO BMI OF THE SUBJECTS

S.No.	BMI	With MetS N=74	Without MetS N=106	Total N=180	Percentage IDF	P value
1	18.5-24.9	9	44	53	16.98	0.000*
2	25-29.9	29	19	48	60.42	
3	≥30	36	43	79	45.57	

***p<0.05**

Figure 9: IDF BASED DESCRIPTION OF METS ACCORDING TO BMI OF THE SUBJECTS

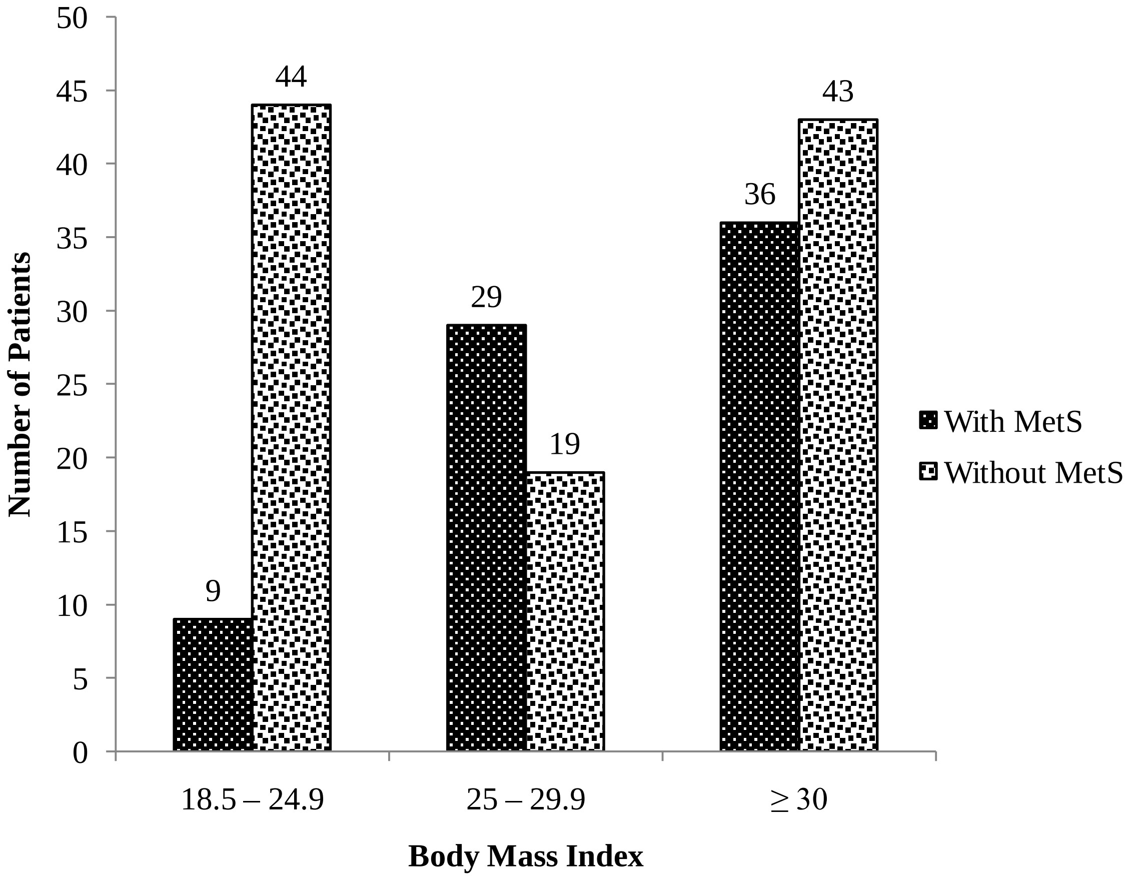

Figure 10: GENDER WISE PREVALENCE OF METS ACCORDING TO rNCEP ATP III DEFINITION

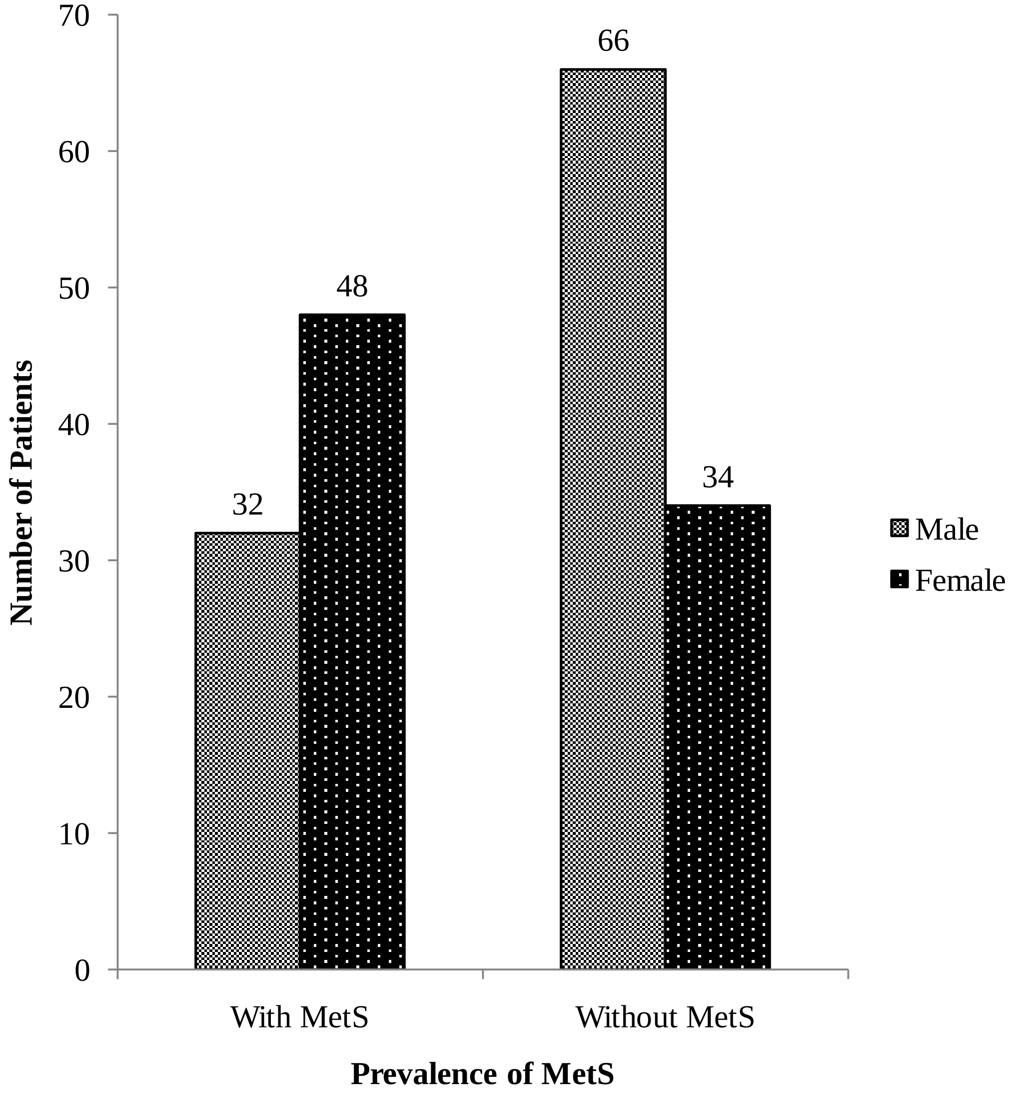

Table 11: PREVALENCE OF METS AMONG THE STUDY POPULATION BASED ON rNCEP ATP III

S. No.	Variables	N=180	Subject with MetS	Percentage of rNCEP
1	**Age in years**			
	a. 20-39	22	06	27.27
	b. 40-59	100	32	32.00
	c. 60-79	58	42	72.41
2	**Sex**			
	a. Male	98	32	32.65
	b. Female	82	48	58.54
3	**Marital status**			
	a. Single	4	2	50.00
	b. Married	176	78	44.32
4	**Educational status**			
	a. ≤ 8	78	44	56.41
	b. 9-11	57	23	40.35
	c. ≥ 12	45	13	28.89
5	**Lifestyle Variables**			
	a. Smoking	20	5	25.00
	b. Alcoholic	10	2	20.00
	c. Both	40	26	65.00
	d. None	110	47	42.72

Table 12: PREVALENCE OF METS AMONG DIFFERENT AGE GROUPS BASED ON rNCEP ATP III DEFINITION

S. No.	Age Group	With MetS	Without MetS	P value
1	20-39	6	16	0.001*
2	40-59	32	68	
3	60-79	42	16	

***p*<0.05**

Figure 11: PREVALENCE OF METS AMONG DIFFERENT AGE GROUPS BASED ON rNCEP ATP III DEFINITION

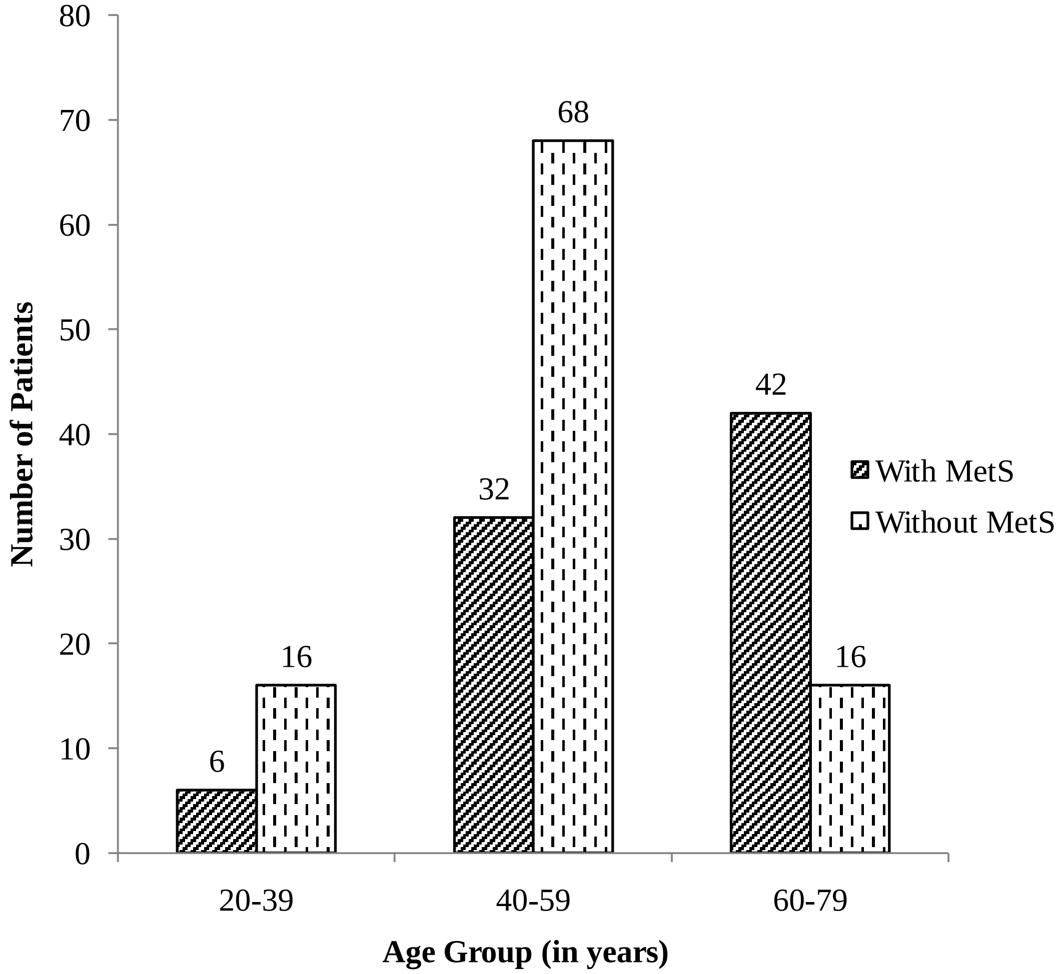

Table 13: PREVALENCE OF METS IN REGARD TO EDUCATIONAL STATUS BASED ON rNCEP ATP III DEFINITION

S. No.	Educational status	With MetS	Without MetS	P value
1	≤ 8	44	34	0.009
2	9 – 11	23	34	
3	≥ 12	13	32	

Figure 12: PREVALENCE OF METS IN REGARD TO EDUCATIONAL STATUS BASED ON rNCEP ATP III DEFINITION

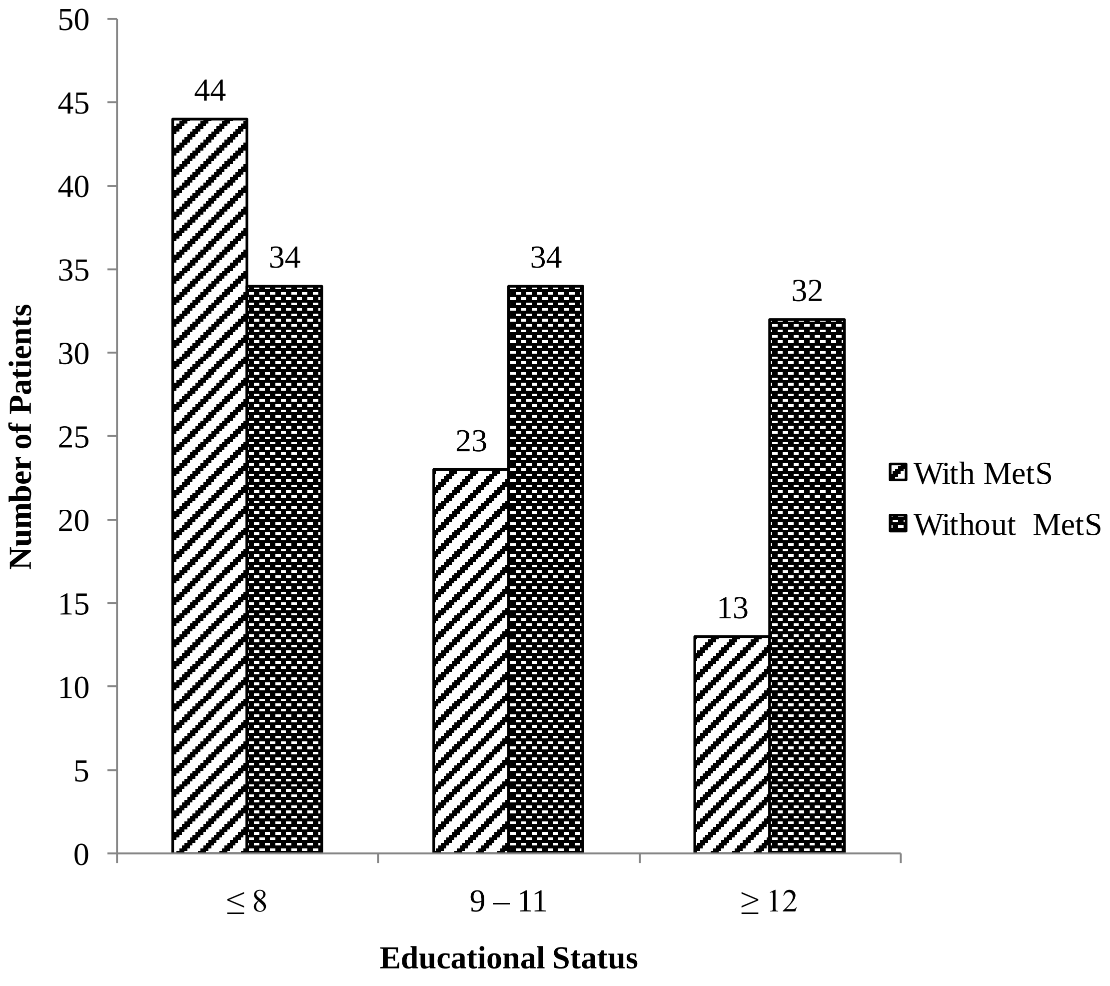

Table 14: CATEGORIZATION OF THE SUBJECTS WITH RESPECT TO BMI BASED ON rNCEP ATP III DEFINTION

S.No.	BMI	With MetS N=80	Without MetS N=100	Total N=180	Percentage of rNCEP	P value
1	18.5 – 24.9	11	42	53	20.75	0.000*
2	25 – 29.9	30	18	48	62.50	
3	≥ 30	39	40	79	49.36	

***p*<0.05**

Figure 13: CATEGORIZATION OF THE SUBJECTS WITH RESPECT TO BMI BASED ON rNCEP ATP III DEFINTION

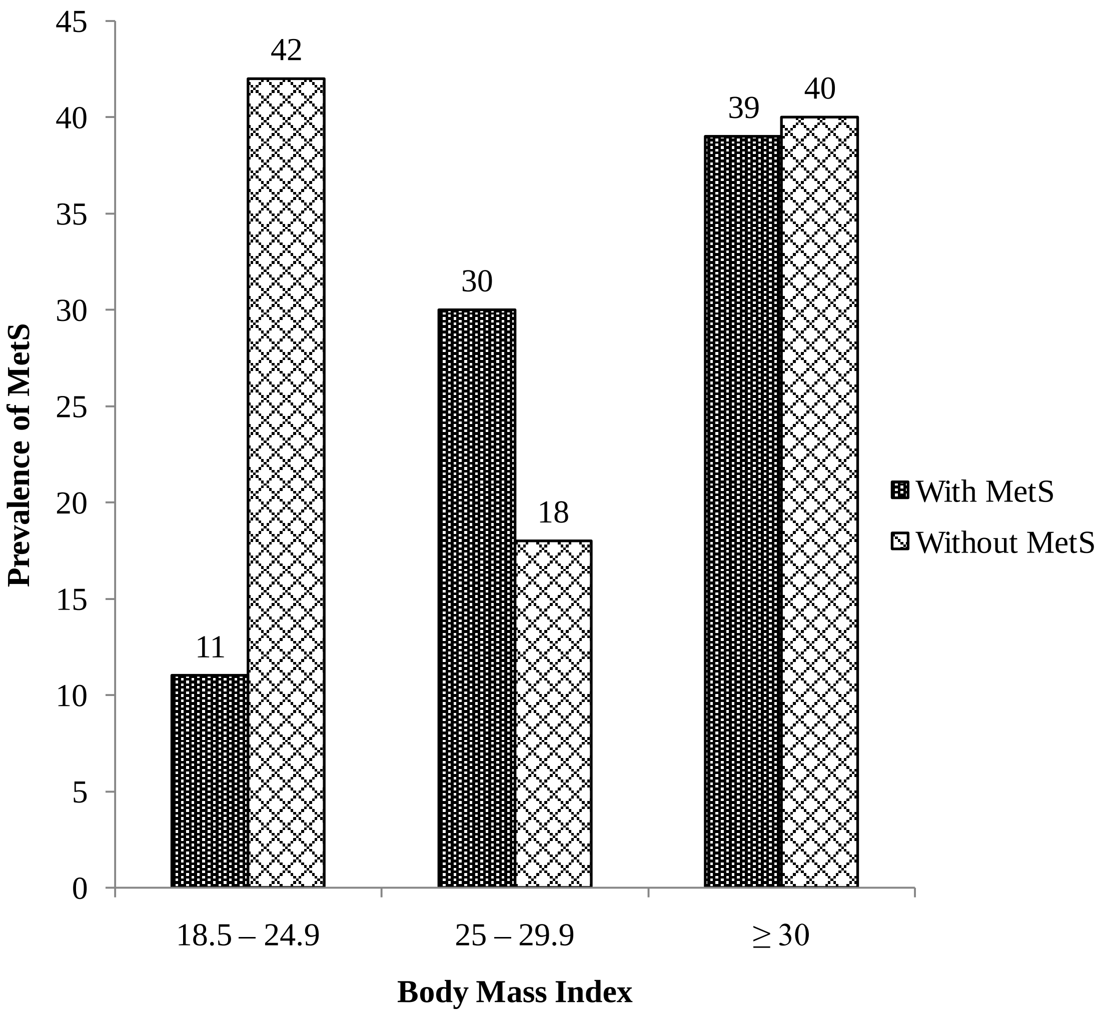

Table 15: COMPARING THE PREVALENCE OF METS BY USING IDF AND rNCEP ATP III DEFINITIONS

Gender	N=180	MetS by IDF	Percentage IDF	MetS by rNCEP	Percentage rNCEP
Male	98	32	32.65	32	32.65
Female	82	42	51.22	48	58.53
Total	180	74	41.11	80	44.44

Figure 14: COMPARING THE PREVALENCE OF METS BY USING IDF AND rNCEP ATP III DEFINITIONS

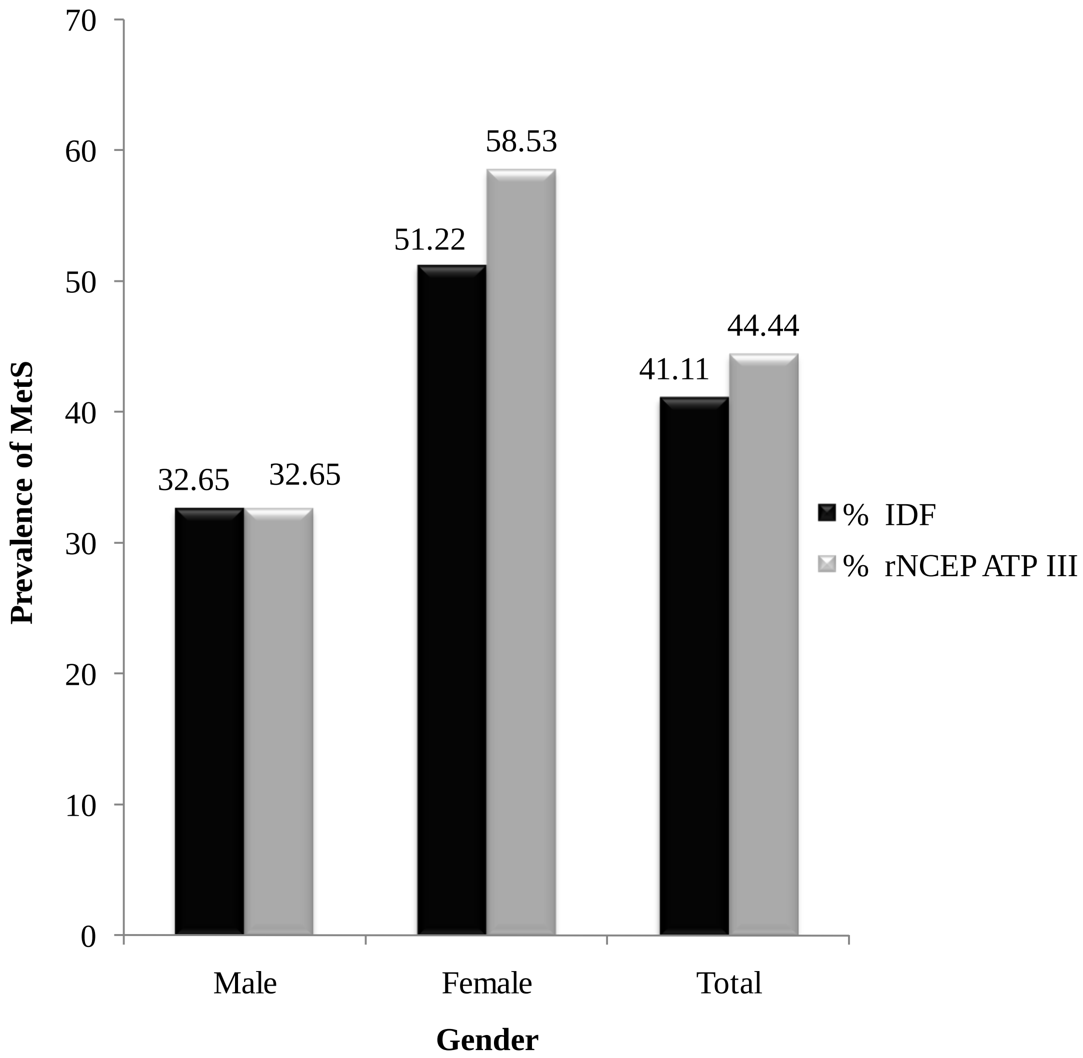

Table 16: COMPARISON OF THE STUDY POPULATION ON BASELINE AND REVIEW

S. No.	General Characteristics	BASELINE (N=180)		REVIEW (N= 104)	
		MALE (MEAN±S.E)	FEMALE (MEAN±S.E)	MALE (MEAN±S.E)	FEMALE (MEAN±S.E)
1	Age in years	54±1.25	55.52±1.38	51.65±1.23	50.54±1.19
2	BMI in kg/m^2	27.27±0.38	28.20±0.34	27.75±0.49	28.72±0.45
3	Waist Circumference in cm	87.97±0.92	84.26±0.82	87.88±1.15	86.40±0.94
4	FBS in mg/100ml	132.61±6.09	156.02±8.33	124.15±7.01	110.63±5.90
5	HDL-c in mg/100ml	47.84±0.98	40.24±1.02	48.53±1.07	39.75±1.58
6	Triglycerides in mg/100ml	130.51±5.99	110.04±3.96	132.1±8.20	120.75±6.36
7	Systolic BP in mmHg	128.57±1.70	130.97±1.77	131.83±2.02	129.77±2.61
8	Diastolic BP in mmHg	81.12±1.05	83.17±1.06	83.33±1.29	83.40±1.45

Table 17: CHARACTERISTICS OF SUBJECTS ACCORDING TO IDF CRITERIA

VARIABLES	WITH METS	WITHOUT METS	OR	95%CI	RR	95%CI	P value
W.C							
Abnormal Normal	74 0	32 74	341.55	20.53 to 5681.69			0.0001*
Laboratory Variables							
TG							
Abnormal Normal	20 54	18 88	1.81	0.88 to 3.72	1.59	0.91 to 2.79	0.1059
HDL-c							
Abnormal Normal	42 32	58 48	1.08	0.59 to 1.97	1.03	0.79 to 1.35	0.7856
FBS							
Abnormal Normal	45 29	36 70	3.02	1.63 to 5.59	1.79	1.29 to 2.47	0.0004*
Hemodynamic Variables							
Systolic BP							
Abnormal Normal	60 14	38 68	7.67	3.79 to 15.51	2.26	1.71 to 2.98	0.0001*
Diastolic BP							
Abnormal Normal	57 17	39 67	5.76	2.95 to 11.26	2.09	1.58 to 2.76	0.0001*

***$p<0.05$**

Table 18: CHARACTERISTICS OF SUBJECTS ACCORDING TO rNCEP ATP III DEFINITION

VARIABLES	WITH METS	WITHOUT METS	OR	95%CI	RR	95%CI	P value
W.C							
Abnormal Normal	74 6	32 68	26.21	10.31 to 66.56	2.89	2.16 to 3.87	0.0001*
Laboratory Variables							
TG							
Abnormal Normal	21 59	17 83	1.74	0.84 to 3.57	1.54	0.87 to 2.72	0.1337
HDL-c							
Abnormal Normal	48 32	52 48	1.39	0.76 to 2.51	1.15	0.89 to 1.49	0.2802
FBS							
Abnormal Normal	51 29	30 70	4.10	2.19 to 7.67	2.12	1.50 to 2.99	0.0001*
Hemodynamic Variables							
Systolic BP							
Abnormal Normal	67 13	31 69	11.47	5.53 to 23.79	2.71	1.99 to 3.68	0.0001*
Diastolic BP							
Abnormal Normal	63 17	33 67	7.52	3.82 to 14.83	2.39	1.76 to 3.23	0.0001*

$*p<0.05$

5. RESULTS AND DISCUSSION

Metabolic syndrome (MetS) is an accumulation of the different conditions that together increases the risk of Cardiovascular Disease (CVD), Diabetes Mellitus (DM), Chronic Kidney Disease (CKD) and is related with a number of other disorders such as sleep apnea, polycystic ovarian disorder (Peters C., 2007). MetS has been shown to increase the risk of CVD morbidity and all-cause mortality. The prevention and reduction of the MetS is essential to reduce CVD and to extend the life of adult population (Mottillo S *et al.*, 2010). The pathogenesis of the syndrome is multifaceted and so far the comprehensive mechanism of causation or its pathophysiology is not completely recognized, however obesity, sedentary lifestyle, dietary factors, and genetic factors are known to interrelate in the development of the syndrome (Cornier *et al.*, 2008). World Health Organization (WHO) [WHO 1999] was the first to propose the criteria for diagnosis of MetS, followed by European Group for the Study of Insulin Resistance (EGIR) [Balkau B *et al.*, 1999]. In WHO and EGIR definitions, the presence of insulin resistance was a prerequisite. The National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP-III) assigned MetS as a secondary target for intervention (Adult Treatment Panel 2001). In 2005, the International Diabetes Federation (IDF) presented a MetS definition (Alberti KG *et al.*, 2005), in which central obesity was the prerequisite and different cut-off values for Waist Circumference (WC) were introduced for different ethnic groups. The American Heart Association and the National Heart, Lung and Blood Institute (AHA/NHLBI) revised the NCEP criteria by decreasing the glucose cutoff from 110 to 100 mg/dl [Grundy SM *et al.*, 2005]. And recently in the revised NCEP ATP III definition a new cut off value for the WC has been introduced for the South Asian population ($\geq$ 90 cm [male], $\geq$ 80 cm [female]).

A prospective observational study was performed to find out the prevalence of MetS using the definitions of revised NCEP ATP III and IDF and to study the impact of different variables such as age, gender, Body Mass Index (BMI), WC, Fasting Blood Sugar (FBS), High Density Lipoprotein cholesterol (HDL-c), Triglycerides (TG) and Blood Pressure (BP) on the study patients based on revised NCEP ATP III and IDF guidelines. A total of 180 patients who visited the Department of Cardiology at Kovai Medical Center and Hospital, Coimbatore from June 2011 to December 2011 were included in our study.

The baseline characteristics of the study subjects were summarized in Table: 1. In the patients who visited the cardiology clinic, 54% (n=98) were males and 46% (n=82) were females within the age group of 20 to 80 years (Table: 2, Figure: 3). The age wise classification of the study patients revealed that 12.22% (n=22), 55.6% (n=100) and 32.22 % (n=58) were in the age group of 20-39 years, 40-59 years and 60-79 years respectively (Table: 3, Figure: 4). The mean age of the men and women patients in the study were 54±1.25 and 55.52±1.38 correspondingly (Table: 1). The average age of the study population was found to be 54.69±0.93 (Table: 16).

Based on lifestyle our study subjects were categorized into smokers, alcoholics, both smokers and alcoholics and abstainers. It was found out that 22.22% were both smokers and alcoholic, whereas 11.11% were smokers and 5.55% were alcoholics alone (Table: 5). A higher number of the study population were found to be both smokers and alcoholics. All the earlier studies depict that smoking and alcohol consumption is a triggering factor for various health hazards in particularly cardiovascular and metabolic complications and so it can be established that these lifestyle variables can be a prompting factor leading to the MetS and in turn leading to cardiovascular complications (Jordan HT *et al.*, 2012).

The study population was categorized based on the level of educational attainment as ≤ 8, 9-11 and ≥ 12 standards. There was about 43% (n=78), 32% (n=57) and 25% (n=45) in ≤ 8, 9-11 and ≥ 12 standards respectively. Majority of the study population who visited the cardiology clinic were having educational qualification ≤ 8 standard.

The factors such as BMI, WC, BP, FBS, HDL-c and TG were measured and documented during the baseline to assess the possibility of the MetS. It was found that during baseline the mean BMI of men was found to be 27.27±0.38 kg/m^2 and that of women was 28.20±0.34 kg/m^2. The average BMI of the study patients was found to be 27.7±0.26 kg/m^2. The mean WC of the male patients was illustrated to be 87.97±0.92 cm and that of females was 84.26 ± 0.82 cm. The average WC of our subjects was 86.29±0.64 cm. The means of the systolic and diastolic BP of men were found to be 128.5±1.70 mmHg & 81.12 ±1.05 mmHg and that of women were 130.97±1.77 mmHg & 83.17±1.06 mmHg correspondingly. The mean systolic and diastolic BP of our study population was found to be 129.66±1.23 mmHg and 82.05±0.75 mmHg respectively. The other clinical parameters such as FBS, HDL-c, and TG of men were found to be 132.61±6.09 mg/100ml, 47.83±0.98 mg/100ml and 130.51±5.96 mg/100ml respectively and for women were 156.02±8.33 mg/100ml, 40.24±1.02 mg/100ml and 110.03±3.96 mg/100ml correspondingly (Table: 1 and Figures: 1 & 2). The average of FBS, HDL-c, and TG of the study patients were found to be 143.27±5.10 mg/100ml, 44.7±0.80 mg/100ml and 121.34±3.78 mg/100ml respectively (Table: 16).

The study patients were categorized based on the IDF and revised NCEP ATP III definitions (Tables: 7 and 11 respectively).

The prevalence of MetS in the study population using the IDF definition was illustrated to be 41%. Similarly to our result, when the IDF criteria was used in another study conducted in Arab population by Harzallah F *et al.,* (2006) a prevalence of 45.5% was observed. Furthermore in another prospective cross sectional study conducted in Mangalore by Pemminatti S *et al.,*(2009) using the IDF criteria, a higher prevalence of the MetS was observed 57% (63.6% in women and 48.8% in men). All these prevalence of the MetS can be associated with our study. Among the 98 male and 82 female subjects, nearly 32 and 42 male and female patients respectively were observed to have the MetS according to the IDF definition. The gender wise prevalence of the syndrome in the study population was found to be 33% (n=32) for males and 51% (n=42) females (Table: 7 and Figure: 7) when using the IDF criteria. It was observed from our study that a higher prevalence of the syndrome was revealed among the female study patients when using the IDF criteria. This gender wise prevalence is in accordance with a study conducted by Mangat C *et al.,* (2010) in the highly urbanized Union Territory of North India, where the prevalence of the MetS was found in 287 (47.4%) subjects and it was more prevalent among females i.e. 171 (59.6%) as compared to males i.e. 116 (40.4%) when using the IDF definition. Similarly Rojas R *et al.,* (2010) conducted a study in Mexico which also revealed a higher prevalence of the MetS in women (52.7%) than men (46.4%) when using the IDF definition. Numerous studies have revealed that women have increased prevalence of the MetS than men according to the IDF definition (Chien KL *et al.,* 2008; Zabetian A *et al.,* 2007) which can be related to our study.

When using the IDF criteria, about 55.17% (n=32) of the study subjects with the MetS were within the age group of 60 to 79 years, subsequently 36% (n=36) and 27.27% (n=6) of the patients were in the age group of 40-59 and 20-39 years respectively (Table: 8 and Figure: 6). A significant association was established between age and the MetS ($p<0.05$) through our study according to the IDF criteria. The prevalence of MetS was found to be highest in the age group of 60 to 79 years. It was observed from our study that there was a progressive development of the MetS in accordance with a sequential increase of the age.

When taking into consideration the educational attainment of the study population, it was found that 54% (n=42), 35% (n=20) and 27% (n=12) of the patients with MetS were in ≤ 8, 9-11 and ≥ 12 standards respectively using the IDF definitions (Table: 8 and Figure: 6). About 54% of the study patients with the MetS had educational qualification ≤ 8 standard. Many literatures have illustrated that low socio-economic status is a predictor for the MetS (Barbosa BJ *et al.*, 2010). Illiteracy and low income has been consistently associated with the MetS in the United States (Ford ES *et al.*, 2004). In developing countries such as India, when comparing the previous outcome of educational status along with the MetS, it was found that majority of the subjects with informal (illiterates) and those with primary education had greater chances of the MetS because of the ignorance of health education, which is comparable to our study.

According to the WHO classification, BMI of our patients were categorized into Normal weight (18.5- 24.9 kg/m^2), Over weight (25-29.9 kg/m^2) and Obese patients (≥ 30 kg/m^2). When using the IDF definition about 17% (n=9), 61% (n=29) and 46% (n=36) of the study patients with the MetS were found to be in Normal weight, over weight and obese categories respectively (Table: 10 and Figure: 9). In our study majority of the patients with the MetS were found to be 'overweight' (61%) and 'obese' (46%) according to the IDF criteria. It has been stated earlier that obesity is linked with insulin resistance and the MetS (Carey VJ *et al.*, 1997). Obesity contributes to hypertension, high serum cholesterol, low HDL-c and hyperglycemia and is independently related with higher CVD risk (Hu G *et al.*, 2004; Zimmet P *et al.*, 2001). The increase in BMI accounts for much of the increase in the prevalence of the MetS (Ford ES *et al.*, 2004) which can be related to our study. And also it was revealed that there was a significant association ($p<0.05$) between BMI and the MetS according to the IDF guidelines.

Based on IDF criteria all the Laboratory and Hemodynamic variables were compared in our study. In the Laboratory variables, TG (OR: 1.8[95% CI: 0.88 to 3.72]; RR: 1.5[95% CI: 0.9 to 2.7; p=0.10]) and HDL (OR: 1.08[95% CI: 0.59 to 1.97]; RR: 1.03[95% CI: 0.79 to 1.35; p=0.78]) revealed that the risk was not statistically significantly different. It was also revealed that when using the IDF criteria the results illustrated that the variables such as FBS (OR: 3.0[95% CI: 1.6 to 5.5]; RR: 1.79[95% CI: 1.2 to 2.4; p=0.0004]), Systolic BP (OR: 7.6[95% CI:3.7 to 15.5]; RR: 2.26[95% CI: 1.7 to 2.9; p=0.0001]) and Diastolic BP (OR: 5.7[95% CI:2.9 to 11.2]; RR: 2.1[95% CI: 1.5 to 2.7; p=0.0001]) had statistically significant association with the MetS (Table: 17).

According to the revised NCEP ATP III definition the prevalence of the MetS was revealed to be 44% of the study population. When using the NCEP ATP III criteria Hu G *et al.*, (2008) revealed that the prevalence of MetS was 39.1% in Finland population and in another study performed by Can AS *et al.*, (2007) using the NCEP ATP III definition established that the prevalence of the syndrome was 38% in Turkish adults; all these results are analogous to our study. The gender wise distribution showed that 32.65% (n=32) and 58.54% (n=48) of men and women respectively had the MetS when using the revised NCEP ATP III definition (Table: 11 and Figure: 10). Even while using the revised NCEP ATP III definition, a higher prevalence of the MetS was observed in women than men. Various data substantiate to our result. For instance, in a study conducted by Ford ES *et al.*, (2005) in the United States with 3601 participants with age ranging from 20 to 70 years, the prevalence of MetS was 34.5% according to the NCEP ATP

III definition (33.7% among men and 35.4% among women). Likewise, in Denmark a study was conducted with 2493 subjects aged between 41 and 72 years showed a 16% (14.3% for men and 18.6% for women) according to NCEP ATP III (Jeppesen J *et al.*, 2007). Similarly in another study conducted in Brazil by Barbosa BJ *et al.*, (2010), revealed the prevalence of MetS was found to be 48.9% in men and 59% in women. All these studies depicted a higher prevalence of the MetS among women which is in accordance with our study and it was established that women are more prone to have MetS and the complications of CVD and T2DM.

Based on the revised NCEP ATP III definition 72.41% (n=42) of our individuals with the syndrome were in the age group of 60-79 years, simultaneously 32% (n=32) and 27.27% (n=6) of the subjects with the MetS were within the age group of 40-59 and 20-39 years correspondingly (Table: 12 and Figure: 11). From our study it was established that there was significant association between age and prevalence of the MetS ($p<0.05$) according to the revised NCEP ATP III definition. Previous studies have illustrated that regardless of the definition of the MetS employed, the prevalence of MetS increases with age (Ford ES *et al.*, 2002; Meigs JB *et al.*, 2003). The prevalence of MetS in our study was found to be higher in patients with age >60 years according to the revised NCEP ATP III definition which resembles to various studies (Kohli P *et al.*, 2006; Qiao Q *et al.*, 2009; Misra R *et al.*, 2009). Similarly in another study conducted using the third National Health and Nutrition Examination Survey (NHANES III) in the USA, exhibited the prevalence of the MetS (defined using NCEP ATP-III criteria) was found to be 6.7% and 43.5% among subjects aged 20-29 years and 60-69 years of age respectively and was 42.0% for participants of 70 years or older (Weiss R *et al.*, 2004). The complications associated with cardiovascular events increases with advancement of age. From the present study it was observed that there was a gradual progress of the syndrome with the increase in age according to the revised NCEP ATP III definition.

According to the revised NCEP ATP III criteria 57% (n=44), 40% (n=23) and 29% (n=13) of the patients with the MetS were in ≤ 8, 9-11 and ≥ 12 standards respectively (Table: 13 and Figure: 12). From our study it was found that majority of the patients with the syndrome had only informal or primary education i.e. below ≤ 8 and therefore may have low socio-economic status and inadequate awareness of health education compared to those with education above ≥ 12 standards.

When considering the impact of BMI on the MetS based on the revised NCEP ATP III definition about 21% (n=11), 63% (n=30) and 50% (n=39) of the patients with the MetS were found to be Normal weight, over weight and obese correspondingly (Table: 14 and Figure: 13). In the study most of the patients with the MetS were 'over-weight' (63%) and 'obese' (50%) based on the revised NCEP ATP III criteria. Previous evidences ascertain that the chances of getting cardiovascular and metabolic complications are higher in 'over weight' and 'obese' patients (Barbosa BJ *et al.,* 2010; Eapen D *et al.,* 2009). Obesity can influence the development of other risk factors, and greater the degree of overweight, the larger the likelihood of developing other antecedents of atherosclerosis such as high blood pressure and type 2 Diabetes Mellitus (T2DM) that will increase the probability of developing CAD. Therefore it was established that obesity and over weight are the driving force to MetS (Ford, Giles and Mokdad, 2004). The present study also conforms that 63% were overweight and 50% were obese patients. The worldwide increase in the prevalence of obesity in the recent decades is staggering and is likely a cause of the rising rate of insulin resistance and the MetS. Although not all overweight or obese individuals are metabolically unhealthy, the majority are insulin resistant. In particular, the combination of obesity, physical inactivity, and consumption of an atherogenic diet is believed to lead to insulin resistance. However, many studies have previously reported a positive association between BMI and MetS (Ford ES *et al.*, 2004; Mangat C *et al.*, 2010; Scott CL., 2003). Our study also resembles to the previous studies and it was found out that there was significant association ($p<0.05$) between BMI and the MetS according to the revised NCEP ATP III definition.

When comparing the laboratory and hemodynamic variables based on the revised NCEP ATP III definitions, there was statistically significant association of the variables such as WC (RR: 2.89[95% CI: 2.15 to 3.8; p=0.0001]), FBS (RR: 2.12[95% CI: 1.5 to 2.9; p=0.0001]), Systolic BP (RR: 2.71[95% CI: 1.9 to 3.6; p=0.0001]) and Diastolic BP (RR: 2.39[95% CI: 1.76 to 3.2; p=0.0001]) with the MetS. The other clinical variables such as HDL-c (OR: 1.38[95% CI: 0.76 to 2.51]; RR: 1.15[95% CI: 0.88 to 1.49; p= 0.2802]) and TG (OR: 1.73[95% CI: 0.84 to 3.57]; RR: 1.54[95% CI: 0.87 to 2.72; p= 0.1337]) were a contributing risk factor for the MetS (Tables: 18). It was known that HDL-c and TG are important clinical variables which trigger the MetS. Our study results revealed that there was a association between these risk factors with the MetS, but it was observed that these risk factors were not significantly associated with the syndrome.

In our observational study two definitions were used to assess the MetS: IDF and revised NCEP ATP III. A total of 180 patients were assessed in this study. The prevalence of MetS was found to be 41% (n=74) according to the IDF definition and 44% (n=80) based on the revised NCEP ATP III criteria. Among the study population, the prevalence of MetS was higher according to both the definitions in females (51% IDF, 59% revised NCEP ATP III) than in males. The age wise distribution revealed a higher prevalence of the MetS within the age group of 60-80 years when using both the definitions.

Our study ascertained that nearly 1/4th of the study population was affected by the MetS, which is similar to the studies performed in various parts of India. In a previous study conducted in South India the prevalence of the MetS was estimated to be 25.8%, 23.2% and 18.3% by IDF, WHO and NCEP ATP III definitions respectively (Deepa M *et al.*, 2007). The vital check points from our study are that prevalence of the MetS increases with advancement of age and a higher prevalence of the MetS was recognized in the female population. The earlier studies conducted in various parts of India by Ramachandran A *et al.*, Gupta R *et al.*, Deepa M *et al.*, Pemminatti S *et al.*, have unanimously shown similar outcomes.

Currently economic growth, irregular timings of meals and dietary westernization has been recommended as possible culprits concerned in the development of the MetS. An increased prevalence of the MetS was observed among patients with increased BMI. The increase in the prevalence of metabolic derangements was related with abdominal adiposity that leads to morbidity and mortality (Pladevall M *et al.*, 2006). In our study it was noted that the prevalence of the MetS according to both the definitions was higher in patients with BMI of 25-29.9 kg/m^2 (Over weight) followed by ≥ 30 kg/m^2 (Obese). It was recognized that the cut off values of BMI for the study population be set at 23 kg/m^2. Several data have substantiated this result. Various studies have shown that the optimal BMI for the South Asians be maintained between 18.5 and 23 kg/m^2 (Eapen D *et al.*, 2009). Another analysis of the Chennai Urban Epidemiology Study (CURES) also demonstrated that the optimal BMI cut-off for identifying the cardiometabolic risk factors was 23 kg/m^2 for Indians of both genders (Mohan V *et al.*, 2007). Likewise in another study conducted by Razak F *et al.*, among 289 South Asian migrants residing in Canada revealed that the BMI cutoff points were 22.5 kg/m^2 for the lipid metabolism and 21 kg/m^2 for glucose metabolism. Findings such as these have prompted the Indian Health Ministry to release a statement defining overweight in both the genders of the country as a BMI >23.0 kg/m^2 and obesity as a BMI >25.0 kg/m^2(iGovernment Press Release).

With the MetS driving the twin global pandemic of T2DM and CVD there is a devastating moral, medical and economic imperative to identify those individuals with the MetS early, so that lifestyle interventions and treatment may prevent the development of T2DM and CVD.

6. CONCLUSION

The Indian subcontinent is undergoing epidemiological evolution as non-communicable ailments like Coronary Heart Disease (CHD) and Type 2 Diabetes Mellitus (T2DM) are rapidly replacing infections as the primary cause of morbidity and mortality. India has developed into the "Diabetes Capital" of the globe and by the year 2020, is expected to have the maximum number of individuals suffering from cardiovascular disease (CVD) (Yusuf S, Ounpuu S., 2001). Approximately 7.8% of the United States (U.S) population has Diabetes Mellitus (DM), and it is expected that the number of patients with DM will increase to 48.3 million by 2050 in the U.S. and to 300 million worldwide in the year 2025, representing a 122% rise compared with 1995. Even though the traditional cardiovascular jeopardy factors (e.g., smoking and hypertension) are becoming more efficiently managed, a permanent increase of the so-called "cardiometabolic risk" is prominent. Early from this century, the nomenclature "Metabolic Syndrome (MetS)" has become more accepted to recognize a cluster of disorders together with obesity, dyslipidemia, hypertension, and insulin resistance. It is the most important risk factor for CVD and DM in both genders. Global cardiovascular jeopardy is the likelihood of affliction of a coronary episode or stroke deriving from risk factors including metabolic factors (total cholesterol, high-density lipoprotein cholesterol (HDL-c), blood glucose), hemodynamic factors (blood pressure), and lifestyle factors (exercise, smoking), all changeable ahead of those nonmodifiable ones such as age and gender.

Ongoing investigation is required to determine how best to define the MetS. Although it is clear that the presence of the syndrome is associated with increased cardiovascular risk, the levels of associated risk have not been clearly defined. Different projected definitions would appear to result in diverse predictions of risk and appears to vary according to which components of the proposed definitions are present. Imam et al., reported a prevalence of 79.7% from Pakistan, Bruno et al., reported a prevalence of 75.6% from the USA and Foucan et al., reported a 77% prevalence of the MetS in diabetic Indian immigrants in the USA.

This prospective study revealed the prevalence rate of the MetS in Outpatient Department of Cardiology clinics among patients with CVD using the IDF criteria as 41.1% and with revised National Cholesterol Education Program Adult Treatment Plan III (rNCEP ATP III) criteria as 44.4%. When studying prevalence among the genders, females were more prevalent to the syndrome than males which give an inference that females with MetS are prone to CVD and other co-morbidities. But there were no significant differences in the cardiometabolic variables, laboratory variables, hemodynamic variables and physical variables among male and female. The findings from our study showed that the prevalence of the MetS increases with age. The prevalence of the MetS in our subjects is high in both genders and increases with age thus posing a latent high cardiovascular risk.

The imperative clinical effect of the MetS was CVD. Also the risk for T2DM is higher, and thereby DM is a foremost risk factor for CVD. Overall, MetS was related with a twofold increase in the risk of CVD and stroke, and a 1.5-fold increase in risk of all-cause mortality. Accordingly, individuals with MetS are at higher risk for cardiovascular outcomes than for all-cause mortality, although these patients are at elevated risk for either outcome compared with those without this syndrome.

The alarming increase in obesity especially its central component consequential in MetS, seems to be behind the twin pandemic of CVD and T2DM currently sweeping the Indian subcontinent. From our study it was revealed that sedentary life-style and increased popularity and easy-availability of energy-dense food are the dynamic force for this increasing hazard. It was found that in people without the syndrome has atleast one component of MetS and may therefore be at an increased risk of cardiometabolic syndrome. And therefore community based programmes to promote healthy living are needed to embark upon this catastrophe. Physicians along with pharmacist and other healthcare professionals have a very important role to play in this endeavor. Therefore larger prospective studies in other parts of India are necessary to recognize the prevalence of the MetS along with the risk factors associated in cross sectional population and in specific groups of high-risk patients.

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